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ENVIRONMENTAL SENTINEL BIOMONITOR TECHNOLOGY ASSESSMENT

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The U.S. Army Center for Environmental Health Research, with support from the U.S. Army Medical Research and Materiel Command, is developing an Environmental Sentinel Biomonitor (ESB) system to provide rapid toxicity identification for a broad spectrum of chemicals in water. A critical initial phase of the study was to test and evaluate toxicity sensor technologies (also called ESB system technologies). Because there were a number of potentially feasible technologies that could meet the goals of the ESB program, a downselection was performed to evaluate these technologies and select the most promising technologies for further development as part of an ESB system. The methodology and process to complete the downselection was developed with user representatives and technology experts. The methods and processes used produce repeatable, defensible, and justifiable investment decisions.

15. SUBJECT TERMS

Environmental Sentinel Biomonitor	Concept of operations	Water monitoring
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Short-term military exposure guidelines	Rapid toxicity identification	Decision analysis
Toxic industrial chemicals and materials	Threshold requirement	Downselect

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PREFACE

The work described in this report was completed with support from the U.S. Army Medical Research and Materiel Command. The work described in this report was started in September 2009 and completed in August 2010.

This final report was prepared in response to a request from the U.S. Army Center for Environmental Health Research (USACEHR) to develop a methodology to evaluate Environmental Sentinel Biomonitor (ESB) technologies and then to evaluate and downselect the most appropriate ESB technologies to further develop into an ESB system.

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ENVIRONMENTAL SENTINEL BIOMONITOR TECHNOLOGY ASSESSMENT

1. OVERVIEW

The Environmental Sentinel Biomonitor (ESB) system downselection process was conducted in FY09–FY10.* An initial assessment, completed in July 2010, was followed by a collection of additional technical data for six of the highest scoring ESB technologies to support a final selection of the technologies for the ESB. Although this report focuses on the initial technology assessment, the results of the final toxicity selection process are also summarized.

1.1 Introduction

The U.S. Army Center for Environmental Health Research (USACEHR), with support and funding from the U.S. Army Medical Research and Materiel Command, is developing an ESB system to provide rapid toxicity identification for a broad spectrum of chemicals in water. The focus of the ESB system is to detect toxicity associated with non-militarized chemicals (i.e., toxic industrial chemicals [TICs] and toxic industrial materials [TIMs]) in Army field drinking water.

A critical initial phase of this research is to test and evaluate ESB technologies. There are a number of potentially feasible technologies that could meet the goals of the ESB program, so a downselection was performed to evaluate these technologies and select the most promising ones for further development.

1.2 Background

Deployed U.S. forces face the possibility of drinking water exposed to a wide range of toxic industrial or agricultural chemicals as a result of normal use (e.g., farm run-off), damaged infrastructures, accidental spills, or deliberate chemical contamination of water. This is true even with water treated with a reverse osmosis-based treatment system; although highly effective at removing most chemicals, reverse osmosis technology is not 100% effective. Chemicals that are present in high concentrations in source water may not be removed to a level sufficient for safe drinking.

Currently, there are no rapid-detection capabilities for the thousands of TICs that soldiers could ingest. Preventative medicine (PM) personnel test water using the water quality analysis set-PM (WQAS-PM). Unfortunately, the WQAS-PM tests for only a few chemicals. Comprehensive tests for TICs require water samples to be sent to a laboratory and can take days to weeks to process.

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* A similar type of assessment was completed in FY04–05. The report for this assessment was: Kooistra, S.; Walther., J; Wurster, L.; *Environmental Sentinel Biomonitor (ESB) System Technology Assessment*; ECBC-TR-517; U.S. Army Edgewood Chemical Biological Center: Aberdeen Proving Ground, MD, 2006; UNCLASSIFIED Report (AD-A463 721).

Toxicity sensors are available that integrate biological systems with electronic monitoring, which facilitates a rapid response to developing toxicity in water. The ESB system will be used to monitor responses of biological components (e.g., enzymes, cells, tissues, or whole organisms) exposed to water and provide rapid responses and warnings should toxic conditions be present. The ESB system is intended to complement available PM field-testing methods.

1.3 Program Objectives

The ESB program will incorporate current toxicity sensor technologies into a system having the size, weight, and logistical characteristics that are suitable for a range of Army requirements. The ESB will also complement current chemical-monitoring systems and provide rapid toxicity identification for a broad spectrum of chemicals in Army field drinking water supplies. Specifically, the ESB system is to be used by PM personnel as part of the currently used WQAS-PM. The optimal system may be a complementary set of toxicity sensors, which would provide the following:

- Rapid response: Required response time should be within 8 h.
- Sensitivity: One ESB technology may not adequately detect all TICs/TIMs. The assessment will consider which ESB technology provides the best overall response to the test chemicals, and which set of technologies can complement each other by filling gaps in the toxicity response of individual technologies and by providing mutual confirmation of a toxic response.

The ESB prototype system was to be developed to a technology readiness level (TRL) 6 by December 2012 (see Appendix A for descriptions of TRLs).

1.4 Assessment Process Overview

A decision analysis-based methodology was developed to conduct the ESB system downselection. Decision analysis is a structured process for decision-making based on established principles of operations research. The decision analysis process includes systematic development and examination of alternative courses of action to define and clarify available choices and associated advantages and disadvantages. It also includes the thorough documentation of results and associated rationale so that final recommendations can be readily explained and defended. The study consisted of five phases:

1. Form the study and assessment team.
2. Define the technical requirements of ESB system.
3. Identify the candidate ESB technologies and collect the required data.
4. Develop an assessment model.
5. Analyze the results.

2. ASSESSMENT PROCESS AND RESULTS

2.1 Study/Assessment Team Formed

An assessment team was formed in late FY09 to conduct the study. The team was led by Drs. William van der Schalie and Thomas Gargan II (USACEHR) with support from the Decision Analysis Team (DAT) of the U.S. Army Edgewood Chemical Biological Center (ECBC). The assessment team was comprised of Army user representatives (i.e., members of an integrated product team [IPT]) and technical experts from collateral organizations and academia. Appendix B contains a list of IPT members and their affiliations, and Appendix C provides information on the expert panel team.

The role of the user representatives was to articulate the concept of operations (CONOPS) for the Army users of an ESB system. They also defined the technical requirements for the system and helped develop the quantitative downselection assessment model.

The role of the technical experts was to be knowledgeable about the ESB technologies, help develop the assessment model, and then assess the technologies against the model. Although the user representatives had primary responsibility for model development, the input from the technical experts was also important because they provided insight into the technical feasibility of the measures included in the model.

2.2 Technical Requirements Defined

The user representatives developed the ESB system CONOPS (Appendix D) based on the WQAS-PM use scenario prepared by Dr. Steve Richards and Mr. Ginn White from the U.S. Army Public Health Command and on suggestions provided by LTC William Darby from the U.S. Army Medical Department Center and School. This information, along with the system technical requirements for a previously developed ESB field/contingency scenario, was used as a starting point in developing the ESB requirements. The user representatives determined and quantified 22 technical requirements (Appendix E) and noted threshold, minimum, ideal, and preferred requirements. Although these performance requirements are important for ranking alternative toxicity sensor technologies, they are not intended to be the final design specifications for the ESB system.

2.3 Selected and Defined Target-Detection Range

The user representatives determined that the concentration range (upper and lower limits) over which ESB technologies must detect TICs/TIMs was between the short-term military exposure guidelines (MEGs) level and the human lethal concentration (HLC), which assumes consumption of 15 L of water per day by a 70 kg soldier. The MEG standard is based on a 70 kg soldier drinking 15 L/day for 7–14 days (Appendix F). Until more-sensitive ESB technologies become available, the ESB program will *not* focus on detecting TICs/TIMs at more sensitive levels (e.g., long-term MEG or U.S. Environmental Protection Agency measures where the focus is on a chronic-effects level). Until then, the existing analytical chemistry tools will be used to detect TICs/TIMs at chronic-effect levels.

The user representatives felt that the ESB technologies should detect toxicity concentrations closer to the short-term MEG level than the HLC level and that the minimum-detection level must be below the HLC. In addition, detecting toxicity below the short-term MEG level was not desirable because this may have resulted in false positive readings.

2.4 Identified ESB Technology Candidates

After extensive research, 16 possible ESB technologies were initially identified, discussed, and confirmed by the technical experts as technologies to consider (Appendix G). Later, 6 of the 16 technologies were removed from consideration (also listed in Appendix G) because the team determined that the technologies were not sufficiently developed to meet the ESB program requirement to achieve a TRL 6 by December 2012. The 10 technologies to be considered further are listed in Table 1, which also provides a correlation between the proper or full ESB name and the abbreviated ESB name. Note, for the most part, only the abbreviated ESB name is used in this report.

The team determined that there was initially insufficient toxicity response information for a thoroughly comparative assessment of the ESB technologies. Therefore, Dr. van der Schalie directed additional research and testing to acquire this information. Information fact sheets that encompass performance, operational, and logistical information were then created to provide supplemental information to help with the technology assessment (Appendix H provides an example).

Table 1. ESB Technologies

Abbreviation	Full ESB Name
Abraxis	Abraxis (Warminster, PA) organophosphate/carbanate screen
ANP	ANP (ANP Technologies; Newark, DE) acetylcholinesterase test kit
Bionas	Bionas (Bionas GmbH; Rostock-Warnemünde, Germany) toxicity sensor (trout gill)
ECIS (EelB)	Electric cell–substrate impedance-sensing (ECIS) using vertebrate cells (eel brain)
ECIS (Trout Gill)	Electric cell–substrate impedance-sensing (ECIS) using vertebrate cells (trout gill)
Eclox	Enhanced chemiluminescence and oxyradical (Eclox; Hach Company; Loveland, CO) toxicity test
Melanophore	Melanophore toxicity sensor
Microtox and Deltatox	Microtox and Deltatox (Modern Water; New Castle, DE)
Toxichip	Toxichip (bacterial cells)
TOX-SPOT	TOX-SPOT (CheckLight Ltd.; Qiryat-Tiv, Israel) toxicity test

2.5 Quantitative Evaluation Model Developed

The study team created assessment criteria based on the 22 technical requirements. Appendix I provides information that compares model goals and criteria to the 22 technical requirements. The assessment criteria are the core of the evaluation model. The criteria are structured as a hierarchy and are at a level that permits discrimination between the different technologies. High-level criteria, referred to as goals, are performance, operational impact, and logistics. Subcategories of criteria, referred to as “measures”, were developed to provide the degree of discrimination needed for the technology evaluation.

A decision-making support software tool, Logical Decisions for Windows (LDW; Logical Decisions, Inc.; Fairfax, VA; copyright 2004), was used to develop and document the technology downselection evaluation model. The model was comprised of eight measures. Measures are composed of definitions and performance scales. Several factors were considered when developing the assessment measures. Assessment measures need to provide differentiation between the ESB technologies, so the measures had to be discriminating. Measures also had to be independent, so that aspects evaluated in one measure were not repeated in another. It was likewise important to focus on the measures that were most critical to the analytical process (i.e., relevant).

Measures can be quantitative and/or qualitative. For example, the *Chemical Detection* measure was quantitative, and its units were the number of chemicals detected. The *Demands on the User* measure was qualitative, and it was assessed in more subjective terms such as “high demands on user.”

Definitions and performance scales are important elements when describing a measure. Measure definitions are narrative descriptions that must be adequately and appropriately stated and clearly understood. Performance scales are the “rating scheme” used to evaluate technologies against a measure. Some performance scales may be continuous (e.g., numeric range for the *Chemical Detection* measure), while others may be discontinuous or discrete levels referred to as “labels” (e.g., temperature range requirements with the *Environmental Conditions During Testing* measure). These two examples are shown in Table 2.

Table 2. Rating Scheme for Measures Example

Utility	**Performance Scale**
Chemical Detection	
100	Continuous: 14 chemicals detected
0	Continuous: 3 chemical detected
Environmental Conditions During Testing	
100	Label: High (>20 °C temperature range)
50	Label: Medium (10–20 °C temperature range)
0	Label: Low (<10 °C temperature range)

Performance scales are expressed as utility functions, which convert different measures to common units. To set relevant endpoints and establish appropriate intermediate utility values, the characteristics of the ESB technology had to be well-defined. Utility values of 100 and

0 were assigned to the high and low ends of each performance scale, and intermediate-level utilities were derived through various elicitation techniques that focused on the relative importance of moving to-and-from various points on the utility function.

Figure 1 illustrates the intermediate utility points, in the form of a utility curve, for the *Test Turn-Around Time* measure. This utility curve is referred to as a "risk-seeking" curve; where the rate of utility increase rises as the desired end of the scale (20 min) is approached. Utility can also be defined by risk-averse and linear curves.

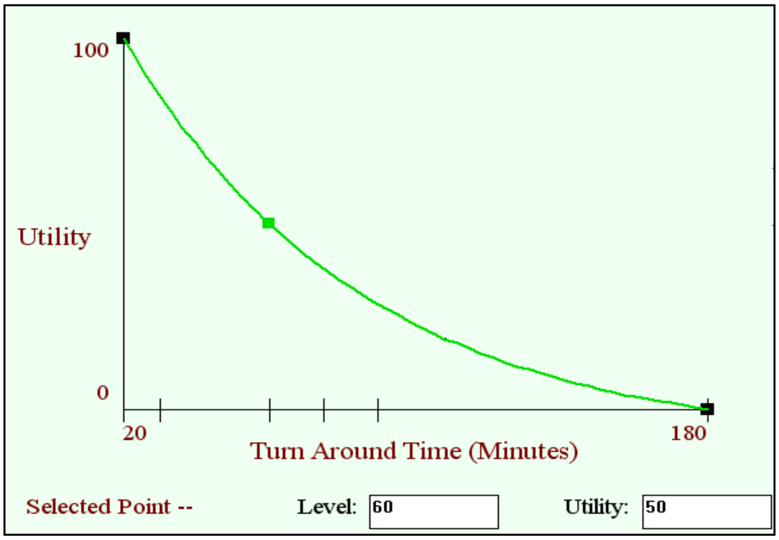

Figure 1. *Test Turn-Around Time* measure utility curve example.

The final model-development step was to weight the measures based on their importance relative to the other measures. Measure-weighting considers both relative priority and the concept of swing-weighting. Swing-weighting compares the effects of movement from the lowest point on the performance scale to the highest point for any measure in relation to a similar move for any other measure. An example would be to determine whether it was more important to move from 180 min to 20 min for the *Test Turn-Around Time* measure when compared with moving from low to high for the *Environmental Conditions During Testing* measure.

Two weighting techniques (Simple Multi-Attribute Rating Technique Exploiting Ranks [SMARTER] method and direct-entry assessment) were used to facilitate the development of the assessment model weights. The smarter method was used as a starting point to establish each measure's rank and initial weight, and then the measure weights were adjusted as necessary with the direct-entry assessment technique because this allowed for a simple, direct entry of the weights.

The DAT developed a draft of the assessment model by converting the already-defined technical requirements into goals and measures. The user representatives, with input from the technical experts, refined this draft and ultimately developed the decision model shown in Figure 2. The model shows the three goals, eight measures, and their weights.

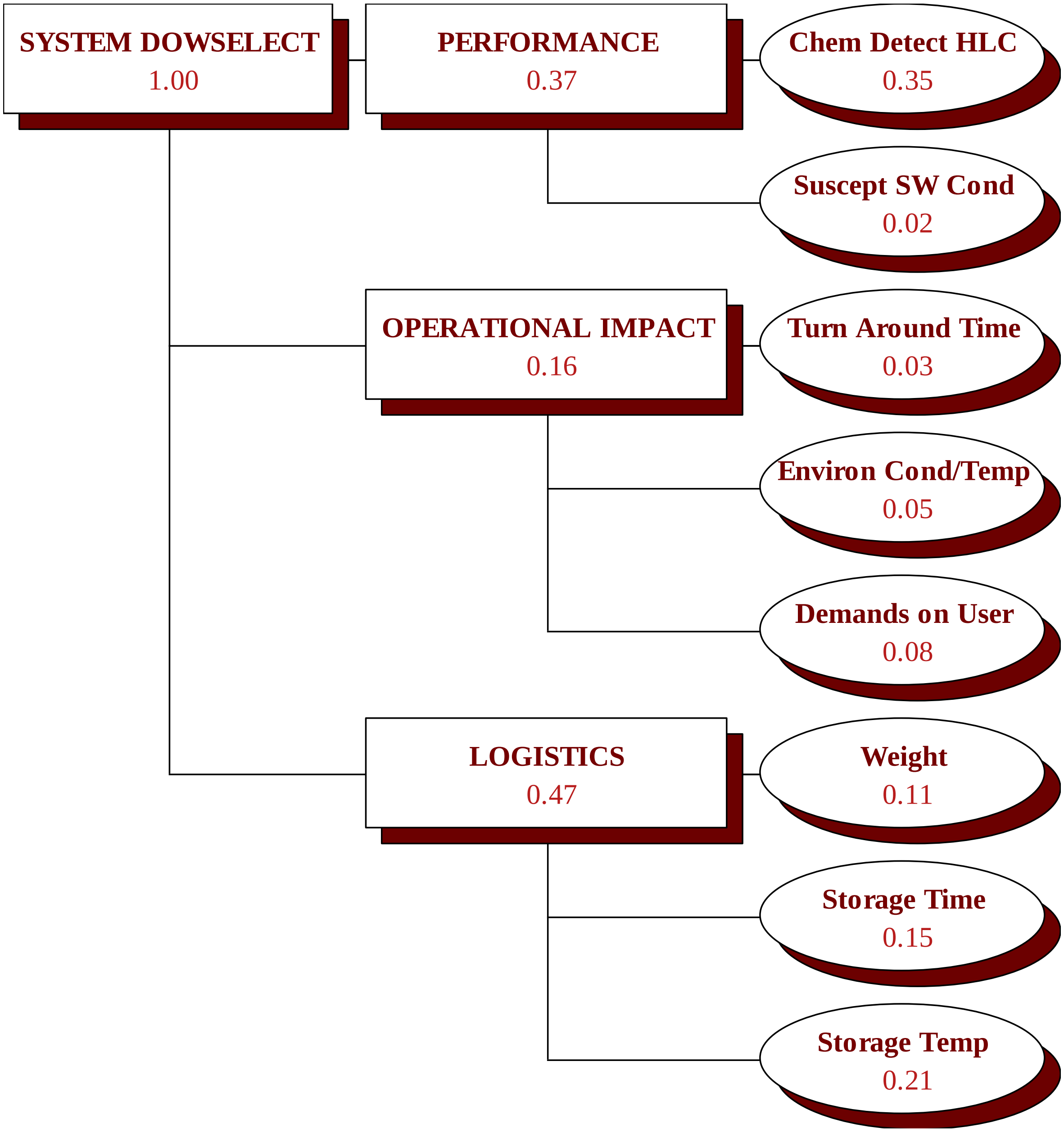

Figure 2. ESB technology downselection decision model.

Table 3 shows the definitions, performance scales, and weights for all eight measures.

Table 3. Model Measure Definitions, Performance Scales, and Weights

Measure (abbreviated model name)	**Definition**	**Performance Scale**	**Weight**
Chemicals Detected *(Chem Detect HLC)*	The ability of the technology to provide a response to a set of representative chemicals at concentrations less than or equal to the HLC. It is better to respond to the greatest number of chemicals less than or equal to the HLC.	100: 14 chemicals 0: 3 chemicals Linear continuous curve	35
Susceptibility to Source Water Conditions *(Suscept SW Cond)*	The ability to operate under a number of source water quality conditions and in the presence of interfering substances (i.e., color, quantity of total dissolved solids, turbidity, humic/fulvic acids, geosmin/MIB, hard water) with minimal effect on test outcome. It is better to be able to operate under a wide range of source water quality conditions than under a more-restricted range.	100: Very low susceptibility (response to none of the tested interferences AND no response to residual chlorine or chloramine); able to operate under a very wide range of conditions and in the presence of interfering substances 75: Low susceptibility (response to none of the tested interferences BUT has a response to residual chlorine or chloramine); able to operate under a wide range of conditions and in the presence of interfering substances 50: Medium susceptibility (response to one of the tested interferences AND has response to residual chlorine or chloramine); able to operate under a moderately wide range of conditions and in the presence of interfering substances 0: High susceptibility (response to two or more of the tested interferences AND has a response to residual chlorine or chloramine); able to operate under a very restricted range of conditions and in the presence of interfering substances Discrete levels	2
Test Turn-Around Time *(Turn-Around Time)*	The longest time required to complete first test. Includes operator set-up time, sample preparation, sensor operation time, and any time required for the system to reset before another reading. It is better to require less rather than more time to perform tests.	100: 20 min 50: 60 min 0: 180 min Nonlinear continuous curve	3
MIB: 2-methylisoborneo			

Table 3. Model Measure Definitions, Performance Scales, and Weights (continued)

Measure (abbreviated model name**)**	**Definition**	**Performance Scale**	**Weight**
Environ-mental Conditions During Testing *(Environ Cond/Temp)*	The range of environmental conditions under which the technology can properly operate. These conditions include the operational air-temperature range for the technology to operate. It is better to be able to operate under all environmental conditions and extremes.	100: High (>20 °C temperature range) 50: Medium (a 10–20 °C temperature range) 0: Low (<10 °C temperature range) Discrete levels	5
Demands on the User *(Demands on User)*	Complexity and user requirements for all phases of the operation and user maintenance. Includes sample preparation and complexity of performing tests (e.g., measuring or adding reagents). The focus is not on the length of each task's performance but on the complexity of each task. It is better for the tasks to be simple (a soldier can perform) rather than complex (a technician must perform at a depot).	100: Low demands on user (low difficulty of use in all three categories*); few steps of preparation; minimal skill level required 50: Medium demands on user (medium/moderate difficulty of use in one of the three categories*; low in the other two categories); some steps of preparation; moderate skill level required (junior water technician [NCO] with lab skills and lab capabilities) 0: High demands on user (medium or higher difficulty of use in two or more of the three categories*); many steps of preparation; significant skill level required (senior water technician with lab skills and lab capabilities) * Categories are sample preparation complexity, level of maintenance required, and skills and knowledge required. Discrete levels	8
Weight *(Weight)*	The weight of the technology (not peripheral storage device or consumables). It is better for the weight to be less rather than more.	100: 1 lb 0: 33 lb Linear continuous curve	11
Storage Time *(Storage Time)*	The storage life of the consumables stored under optimal conditions. It is better for the storage life to be longer.	100: 12 months or more 80: 8 months 0: 1 month Nonlinear continuous curve	15
Storage Temperature *(Storage Temp)*	The optimal recommended storage temperature. It is better not to require any cooling during storage.	100: Room temperature or higher (>20 °C) 50: Refrigerator required (4–12 °C) 0: Freezer required (–20 °C) Discrete levels	21

Technical experts also provided important programmatic insights such as noting risks and the potential to improve the capabilities of ESB technologies (Appendix J). These programmatic decision factors were not included in the model but were considered along with the model's results in the final conclusions and recommendations. Table 4 is an example of an ESB technology programmatic assessment. Programmatic input and comments are sometimes very general because limited programmatic data were available for each technology (most technologies were in an early stage of development) and because of the limited time the technical experts had to complete this assessment.

Table 4. ECIS (EelB) Technology Programmatic Assessment Example

Programmatic Assessment					
ESB Technology	**TRL**	**Reasonable\Expected Improvement (Positive)**	**Concerns (Known)**	**Risks (Unknown)**	**Overall Risk**
ECIS (EelB)	3/4	Storage tests to date have not been longer than a month; will evaluate to see if storage time can be longer than currently scored. Assay temperature range assessed to date has been limited, could be greater. Potential for more than one cell type on a chip (although this would increase cost).	Bio components made by university or individual researcher makes eel-based system riskier and may be less robust. Need to evaluate optimal storage temperature. Need to complete detection-level testing. Need to characterize cell line.	Cells respond to many things (interference issues), which can lead to false positives.	Yellow/Red
Overall Risk Rating Key: Green: The technology is considered to present a low risk of unsuccessful development. Yellow: The technology is considered to present a moderate risk of unsuccessful development. Red: The technology is considered to present a high risk of unsuccessful development.					

2.6 Analysis of Results

The DAT facilitated a 2 day meeting in July 2010 where the technical experts conducted the quantitative downselection evaluation. The technical experts used the ESB technology fact sheets, which were a combination of both quantitative and qualitative data about the ESB technologies, along with their knowledge of similar technologies and mechanisms. The technical experts scored each technology against each evaluation model measure on the basis of the performance scales. Final scores were a consensus of expert judgment and were not an average of the individual technical expert assessments. Assumptions and rationale for scores were documented where necessary.

Overall scores were then calculated for each technology by multiplying the numerical rating for each measure by its weight and summing the scores over all measures (linear additive function). The highest possible score was 100. While the overall scores were important, they were only used as a guide to formulate findings and conclusions.

Analyses of the results were completed by the DAT from three different perspectives. First, the overall results were examined to discern general outcomes and trends. Second, each technology was examined to identify strengths and weaknesses. Third, the results specific to each measure were examined to identify potential technical obstacles or shortcomings. LDW was used in the analysis because it has many useful tools for performing comparative analysis and displaying and documenting results.

2.6.1 Overall Results

Figure 3 shows the overall model score and rank of each ESB technology, and it also shows where each technology was strong or weak, relative to the three goals. Figure 4 shows similar information, but presents a greater level of detail by showing how each technology scored against the eight measures. The length of each of the sub-bars indicates how much of the technology's overall score was attributable to the three goals or eight measures (based on the measure score and weight).

The model results for the ten ESB technologies were categorized into three broad ranking tiers:

- Above Average: ECIS (EelB), ECIS (Trout Gill), and Abraxis
- Average: ANP, Eclox, Melansphore, TOX-SPOT, Deltatox, and Bionas
- Below Average: Toxichip

Figure 3 illustrates that the logistics goal has a significant impact for most of the ESB technology scores. This was mainly due to its high weight (47%; shown in Figure 2). However, ECIS (EelB) had a high overall score, although it did not score high for logistics, primarily because of its performance goal score. Overall, primarily because of its lower weight in the model (37%), the performance goal affected the model less than the other goals. The operational impact goal had the least impact for most of the technologies mostly because this was the lowest-weighted goal (16%). This was best illustrated by Eclox and Deltatox, which scored high for the operational impact goal but scored low overall.

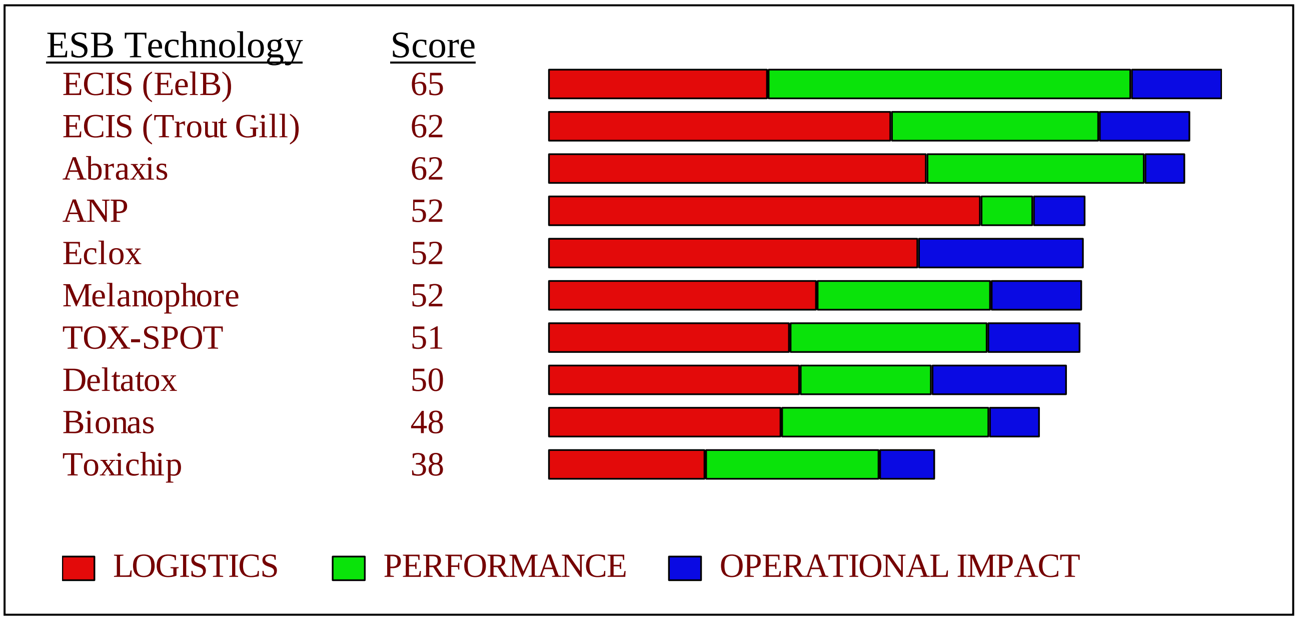

Figure 3. Overall assessment of goal scores for ESB technologies.

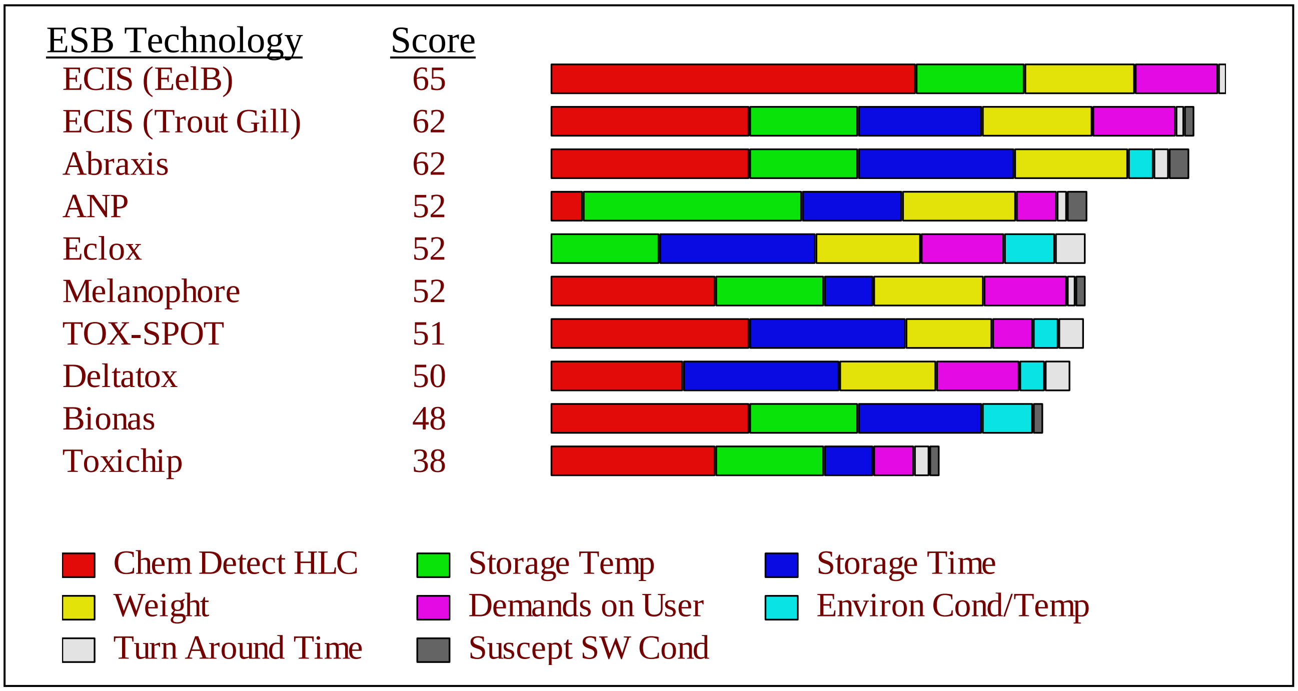

Figure 4. Overall assessment of measure scores for ESB technologies.

2.6.2 Technology Analysis

The purpose of the technology analysis was to highlight areas where particular technologies would stand out, either positively or negatively. Table 5 contains a narrative summary of the relative strengths and weaknesses for each technology using the terminologies "above average" and "below average". These ratings were subjectively determined by the DAT and were based on the score of each ESB technology relative to the other ESB technology scores. In Table 5, the 10 technologies are presented in the ranking order that they scored against the model (i.e., number in parentheses is score [e.g., 65 for ECIS (EelB)]).

Table 5. Technology Strengths and Weaknesses Analysis Narrative Summaries

Rank	**Summary**
1	ECIS (EelB) (65): • Scored above average on three measures (*Chem Detect HLC, Weight,* and *Demands on User).* • Scored below average on three measures (*Storage Time, Environ Cond/Temp,* and *Suscept SW Cond*). • Used to detect 14 chemicals, which was 5 chemicals more than were detected using the other two top-ranked technologies. • Used to detect acrylonitrile (the other technologies did not detect this substance).
2	ECIS (Trout Gill) (62): • Scored above average on three measures (*Storage Time, Weight,*and *Demands on Use*r) • Scored below average on one measure (*Environ Cond/Temp*). • Detected nine chemicals, which was five chemicals less than were detected using the top-ranked technology. • Used to detect arsenic (the three top-ranked technologies did not detect this substance).
3	Abraxis (62): • Scored above average on three measures (*Storage Time, Weight,* and *Suscept SW Cond*). • Scored below average on one measure (*Demands on User*). • Used to detect nine chemicals, which was five chemicals less than were detected using the top-ranked technology. • Detected no additional chemicals when compared with those detected using the two top-ranked technologies.
4	ANP (52): • Scored above average on three measures (*Storage Temp, Weight,* and *Suscept SW Cond*). • Scored below average on two measures (*Chem Detect HLC* and *Environ Cond/Temp*). • Used to detect four chemicals, but no additional chemicals were detected when compared with those from the three top-ranked technologies.

Table 5. Technology Strengths and Weaknesses Analysis Narrative Summaries (continued)

Rank	**Summary**
5	Eclox (52): • Scored above average on five measures (*Storage Time*, *Weight*, *Demands on User*, *Environ Cond/Temp*, and *Turn-Around Time*). • Scored below average on two measures (*Chem Detect HLC*, and *Suscept SW Cond*). • Used to detected only three chemicals, which was the fewest number of chemicals detected. • Detected no additional chemicals when compared with those detected using the three top-ranked technologies.
6	Melanophore (52): • Scored above average on two measures (*Weight* and *Demands on User*). • Scored below average on one measure (*Environ Cond/Temp*). • Used to detect eight chemicals, but no additional chemicals were detected when compared with those detected using the three top-ranked technologies.
7	TOX-SPOT (51): • Did not score above average on any measure. • Scored below average on two measures (*Weight* and *Environ Cond/Temp*). • Used to detect nine chemicals, but no additional chemicals were detected when compared with those detected using the three top-ranked technologies.
8	Deltatox (50): • Scored above average on four measures (*Storage Temp*, *Weight*, *Demands on User*, and *Turn-Around Time*). • Scored below average on two measures (*Storage Temp* and *Suscept SW Cond*). • Used to detect seven chemicals, but no additional chemicals were detected when compared with those detected using the three top-ranked technologies detected.
9	Bionas (48): • Scored above average on two measures (*Storage Time* and *Environ Cond/Temp*). • Scored below average on three measures (*Weight*, *Demands on User*, and *Turn-Around Time*). • Used to detect nine chemicals. • Used to detect nicotine (the other technologies did not detect this substance).
10	Toxichip (38): • Did not score above average on any measures. • Scored below average on two measures (*Weight* and *Environ Cond/Temp*). • Used to detect eight chemicals. • Used to detect paraquat (the other technologies did not detect this substance).

LDW was used to generate strengths and weaknesses charts for each technology. The charts graphically depict the strengths and weaknesses of a particular technology relative to each measure. Figure 5 is an example of such a chart for the ECIS (Trout Gill) technology. The height of the bars indicates a technology's relative score for each measure, and the width indicates the relative weight of the measure. Figure 5 shows that the ECIS (Trout Gill) technology scored very high against three measures: *Storage Time, Weight*, and *Demands on User*, and it scored low against measures that were weighted low. For example the *Turn-Around Time* measure (second to far right bar in Figure 5), is worth 3% of the models' overall weight. Strength and weakness charts for the other technologies evaluated are provided in Appendix K.

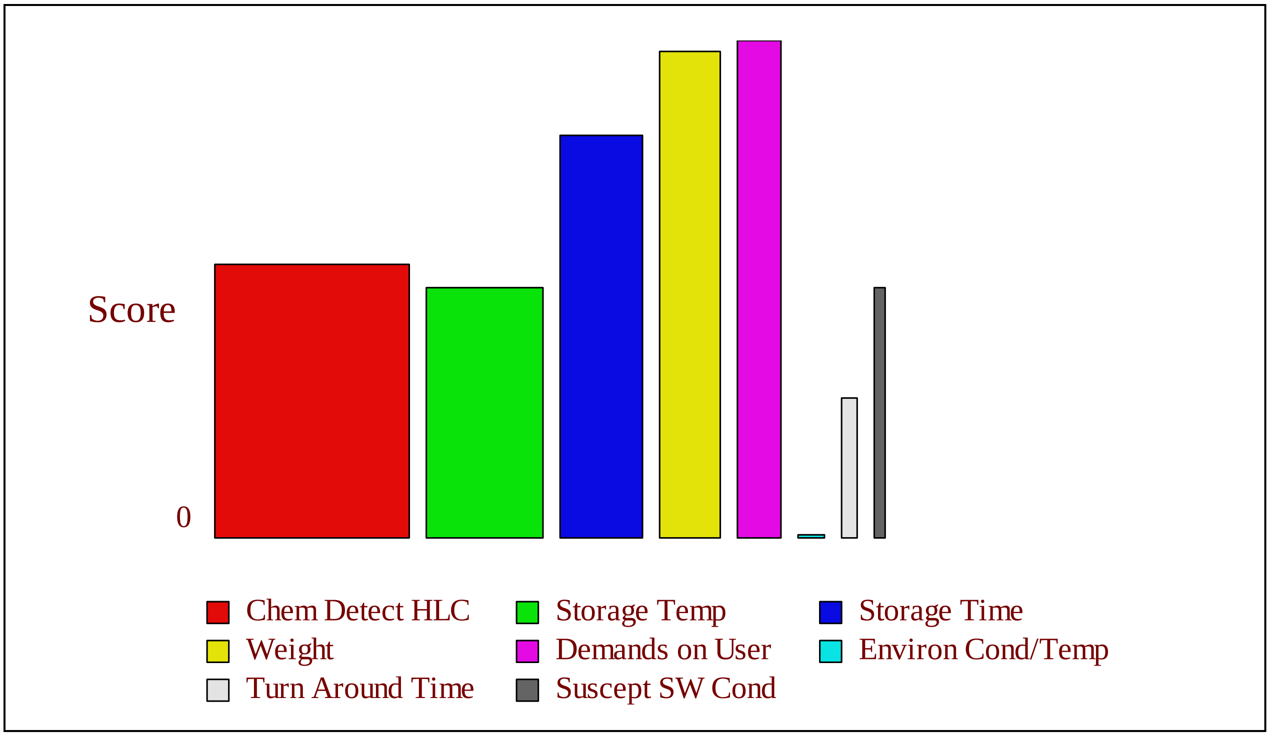

Figure 5. Technology strengths and weaknesses analysis chart for the ECIS (Trout Gill) example.

2.6.3 Measure Analysis

The measure analysis is used to summarize the assessment results in terms of the individual model measures. Because the measures represent user needs, this analysis helps identify areas of shortfall or potential technical challenges (e.g., if most ESB technologies scored low against a measure). Conversely, the analysis also identifies areas of minimal concern (e.g., if all technologies scored high against a measure and/or the measure was low-weighted).

The ranges of scores for each measure were examined to determine overall ESB technology performance relative to each measure, which provided the basis for assignment of a subjective assessment rating by the DAT. Comments and rationale for each measure rating were also provided. Each measure was assessed on a green, yellow, or red scale. Table 6 contains the ratings, rating definitions, weights (in parentheses), and support comments for the eight model measures.

Most measures were rated yellow. The *Weight* measure was rated green because most technologies will meet weight requirements. The *Storage Temp* measure was rated red because the consumables for all assessed toxicity sensors needed at least some degree of temperature control. Users determined that freezing was an unacceptable storage requirement for any ESB technology; however, refrigeration, although not ideal, was nevertheless a possibility.

Table 6. Measure Analysis

Measure (Weight)	**Rating***	**Comments**
Chem Detect HLC (0.35)	Yellow	• This measure was weighted the highest at a third of the model's weight. • Half of the technologies detected less than two-thirds of the test chemicals. • Only one technology detected more than nine chemicals. • An ESB system would be created with two or more technologies, which would reduce reliance on any one technology for the detection of all test chemicals.
Suscept SW Cond (0.02)	Yellow	• This measure was weighted very low and, thus, had a small overall impact on the model's score. • Eight technologies had a score of medium or high (worst score).
Turn-Around Time (0.03)	Yellow	• This measure was weighted very low and, thus, had a small overall impact on the model's score. • Seven technologies earned a mid-range score (50) or worse.
Environ Cond/Temp (0.05)	Yellow	• This measure was weighted low and, thus, had a small overall impact on the model's score. • Half (five) of the technologies scored medium (50) or low (worst).
Demands on User (0.08)	Yellow	• This measure was weighted low and, thus, had a small overall impact on the model's score. • Half (five) of the technologies scored medium (50) or high (worst).
Weight (0.11)	Green	• This measure was weighted moderately high (fourth highest) • Six technologies scored 93 or higher; eight scored 76 or higher.
Storage Time (0.15)	Yellow	• This measure was weighted the third highest and had a fairly significant overall impact on the model's score. • Seven technologies scored 80 or higher; although, the other three scored 32 or lower.
Storage Temp (0.21)	Red	• This measure was weighted the second highest at more than a fifth of the model's weight. • Seven of the technologies scored 50 (required refrigeration) and two scored 0 (freezer required).
*Rating Key: • Green: Area of low concern. Most or all technologies scored high against measure, which indicates that user needs should be met, and/or the measure had a low weight and was unlikely to cause significant impact. • Yellow: Area of moderate concern. Several technologies did not score high against the measure and the measure had a moderate weight, which indicates that user needs may not be met. • Red: Area of high concern. Several technologies did not score high against measure and measure had a high weight or most technologies scored low and measure had a moderate weight. Either result indicates that user needs will probably not be met.		

3. CONCLUSIONS

By creating and using a system of two ESB technologies from the top-tier technologies (Abraxis, ECIS [EelB], and ECIS [Trout Gill]), 15 of 18 test chemicals were detected. However, even with an ESB system made up of all three of the top-tier technologies, two test chemicals were not detected (fluoroacetate and paraquat). Actually, none of the technologies detected fluoroacetate and only the Toxichip technology detected paraquat. (Toxichip was the lowest-scoring technology overall, although Toxichip only had test data for 9 of 18 test chemicals.)

Even the best three ESB technologies only scored in the 62–65 range and had areas within performance, operational impact, or logistics that could have been improved.

All technologies required some kind of temperature control (i.e., refrigeration or freezing) to allow the viable use of the technology for a month or longer. This requirement is a concern for the user community. Such technologies would require temperature-controlled conditions in theater and need a cold chain-shipping process to ensure that they would arrive in a viable condition.

ESB technologies that scored poorly in the model, but can be used to detect an important class of chemicals, may be recommended for further consideration and research. For example, the Toxichip, a technology that had the lowest score, is the only technology known to detect paraquat at the appropriate sensitivity level.

4. RECOMMENDATIONS

In July 2010, the technical experts at the final study meeting recommended further evaluation of the following six technologies, which should include completing the suggested research:

- Abraxis: Approach the Abraxis developer regarding their willingness to reduce the number of steps and simplify the process. If they are willing to take this action, determine if the proposed cost and time-to-accomplish the task is feasible.
- ANP: Retest all 18 test chemicals after an ANP Technologies developer has completed updating one of their key detection processes (i.e., the test-ticket optimization process). Re-evaluate the storage time used with this technology, if more information is available.
- Bionas: Wait to see if the Bionas developer's fluidic chip (under development at the time of this study) was successful. Retest the Bionas technology with methyl parathion to investigate any discrepancy between this company tests versus USACEHR tests.

- ECIS (EelB): Retest this technology to more precisely determine the response for 18 test chemicals between the MEG and the HLC. Characterize the cell line and continue with research to determine the length of storage time (>1 month is needed).

- ECIS (Trout Gill): Continue research to determine if storage time is >8 months.

- Toxichip: Perform government-sponsored tests to determine the responses for the 18 test chemicals. The results available at the time of this study were from the Toxichip developer and were not confirmed independently by the government. First, test to determine if the Toxichip technology detects the test chemicals at the HLC. If so, then test the technology to determine if the threshold for detection was above the MEG or below it.

The following four technologies were not recommended for further consideration:

- Deltatox: Requires freezing for an optimal shelf life. Maintaining freezing conditions during shipping would be very problematic and makes this technology unusable.

- Eclox: Detects only three test chemicals and two of these were below the MEG level.

- Melanophore: There was no reasonable chance to increase the 3 month shelf life; the shelf life is driven by the biology of the technology.

- TOX-SPOT: Requires freezing for an optimal shelf life. Maintaining freezing conditions during shipping would be very problematic and makes this technology unusable.

Decision analysis methodologies and tools can provide a framework to further analyze current and new ESB technologies as additional data from future research becomes available. This effort could be part of a structured reassessment process. Resource allocation methodologies could also be used to model the various funding options for each of the technologies chosen. This would allow the ESB system program managers to perform "what-if" analyses and model for the maximization of benefits while addressing any potential funding cuts or additions.

5. POST-ASSESSMENT TECHNOLOGY EVALUATIONS

After July 2010, the USACEHR conducted additional testing and evaluation of the six technologies recommended by the technical experts (Section 4). The results were as follows:

- ECIS (Trout Gill): The trout gill cells have remained viable and responsive to toxicants when stored at 6 °C for over 12 months on the fluidic biochips used in testing. The IPT selected this toxicity sensor as one of the two ESB

system components because of the long-term viability of its consumable, combined with good sensitivity to a wide range of toxicants.

- ANP: Abraxis and ANP technologies focused primarily on detected acetylcholinesterase inhibition caused by organophosphorus and carbamate pesticides. This was considered an essential capability for an ESB system because none of the other toxicity sensors were sensitive to these materials, and because these chemicals were an important class of environmental contaminants. Retesting the ANP technology using optimized test tickets resulted in excellent detection of organophosphorus and carbamate pesticides through the use of a simple test procedure and consumables that did not require refrigeration. This was the second of two toxicity sensors that were recommended by the IPT for the ESB system.

- Abraxis: The Abraxis developer has been funded to develop a way to reduce the number of steps, simplify the testing process, and provide temperature-stabilized reagents that do not require refrigeration. If they are successful, the Abraxis system will be considered to be a viable alternative to that of ANP Technologies.

- Bionas: Although it shows promise, the prototype Bionas fluidic chip still needs considerable development and can be used only with an instrument that is unsuitable for field use. Whereas the Bionas may someday be suitable for Army needs, at the time of this study there were insufficient time and resources to develop it further for use with the ESB.

- ECIS (EelB): After this study was complete, further testing using EelB cells led to the determination that these cells had excessive false-positive responses to control water and to nonharmful changes in water quality, such as small increases in hardness. EelB cells were determined to be unsuitable for the ESB system.

- Toxichip: Because of issues related to intellectual property concerns, time and resource constraints, and the difficulties involved in dealing with a foreign vendor, it was not possible to independently confirm the performance of the Toxichip bacterial cells or to consider them as a potential component of the ESB system.

In summary, on the basis of further consideration of the six technologies that were recommended as a result of the downselection effort, the best toxicity sensor candidates for inclusion in the ESB system were determined to be the ECIS (Trout Gill) and the ANP Technologies acetylcholinesterase test kit. At the time of this report, plans were made to complete TRL 6 prototypes of these two sensors and take them into a Milestone B review in December 2012.

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ACRONYMS AND ABBREVIATIONS

ac	alternating current
AchE	acetylcholinesterase
ANP	ANP Technologies (Newark, DE)
Bionas	Bionas GmbH (Rostock-Warnemünde, Germany)
CA	commercially available
Chem Detect HLC	Chemicals Detected model
CONOPS	concept of operations
cu	color unit
CV	coefficient of variation
DAT	Decision Analysis Team (ECBC)
dc	direct current
Demands on User	Demands on the User (model)
DoD	Department of Defense
ECBC	U.S. Army Edgewood Chemical Biological Center
ECIS	electric cell–substrate impedance-sensing
Eclox	enhanced chemiluminescence and oxyradical (toxicity test)
EelB	eel brain
EMI	electromagnetic interference
Environ Cond/Temp	Environmental Conditions During Testing model
ESB	Environmental Sentinel Biomonitor
G	green
HazMat	hazardous material
HLC	human lethal concentration
IPT	integrate product team
LDW	Logical Decisions for Windows (software)
LED	light-emitting diode
MEG	military exposure guideline
MIB	2-methylisoborneol
MOS	military occupation skill
NA	not applicable
NTU	nephelometric turbidity unit
O	objective or maximum requirement
PM	preventative medicine
R	red
RDECOM	U.S. Army Research, Development and Engineering Command
SBIR	small business innovation research
Storage Temp	Storage Temperature (model)
Suscept SW Cond	Susceptibility to Source Water Conditions (model)
T	threshold or minimum requirement
TBD	to be determined
TICs	toxic industrial chemicals
TIMs	toxic industrial materials
TRL	technology readiness level
Turn-Around Time	Test Turn-Around Time (model)
USACEHR	U.S. Army Center for Environmental Health Research

USAMMDA	U.S. Army Medical Materiel Development Activity
WQAS-PM	water quality analysis set-preventative medicine
Y	yellow

APPENDIX A

TRL DEFINITIONS[†]

TRL 1 Basic principles observed and reported: Transition from scientific research to applied research. Essential characteristics and behaviors of systems and architectures are known. Descriptive tools are mathematical formulations or algorithms.

TRL 2 Technology concept and/or application formulated: Applied research. Theory and scientific principles are focused on specific application area to define the concept. Characteristics of the application are described. Analytical tools are developed for simulation or analysis of the application.

TRL 3 Analytical and experimental critical function and/or characteristic proof-of concept: Proof of concept validation. Active Research and Development (R&D) is initiated with analytical and laboratory studies. Demonstration of technical feasibility using breadboard or brassboard implementations are exercised with representative data.

TRL 4 Component/subsystem validation in laboratory environment: Standalone prototyping implementation and test. Integration of technology elements. Experiments with full-scale problems or data sets.

TRL 5 System/subsystem/component validation in relevant environment: Thorough testing of prototyping in representative environment. Basic technology elements integrated with reasonably realistic supporting elements. Prototyping implementations conform to target environment and interfaces.

TRL 6 System/subsystem model or prototyping demonstration in a relevant end-to-end environment (ground or space): Prototyping implementations on full-scale realistic problems. Partially integrated with existing systems. Limited documentation available. Engineering feasibility fully demonstrated in actual system application.

TRL 7 System prototyping demonstration in an operational environment (ground or space): System prototyping demonstration in operational environment. System is at or near scale of the operational system, with most functions available for demonstration and test. Well integrated with collateral and ancillary systems. Limited documentation available.

TRL 8 Actual system completed and "mission qualified" through test and demonstration in an operational environment (ground or space): End of system development. Fully integrated with operational hardware and software systems. Most user documentation, training documentation, and maintenance documentation completed. All functionality tested in simulated and operational scenarios. Verification and Validation (V&V) completed.

TRL 9 Actual system "mission proven" through successful mission operations (ground or space): Fully integrated with operational hardware/software systems. Actual system has been thoroughly demonstrated and tested in its operational environment. All documentation completed. Successful operational experience. Sustaining engineering support in place.

[†] *Definition of Technology Readiness Levels*, National Aeronautics and Space Administration, Earth Science Technology Office: Greenbelt, MD. http://esto.nasa.gov/files/trl_definitions.pdf.

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APPENDIX B

ESB SYSTEM TECHNOLOGY ASSESSMENT IPT

First Name	Last Name	Affiliation
Craig	Anderson	U.S. Army Medical Research Acquisition Activity (Fort Detrick, MD)
Charles	Burden	Combined Arms Support Command (Fort Lee, Virginia)
William	Darby	U.S. Army Medical Department Center and School (Fort Sam Houston, TX)
Jay	Dusenbury	U.S. Army Research, Development, and Engineering Command (RDECOM; Aberdeen Proving Ground, MD)
Tom	Gargan	USACEHR (Bethesda, MD)
Teri	Glass	U.S. Army Medical Materiel Development Activity (USAMMDA; Fort Detrick, MD)
Dennis	Goodes	General Dynamics Information Technology; representing the U.S. Army Medical Research and Materiel Command Military Operational Medicine Research Program (Fort Detrick, MD)
Mark	Pettinato	USAMMDA
Steve	Richards	U.S. Army Public Health Command (Provisional) (USAPHC; Aberdeen Proving Ground, MD)
Robert	Ryczak	USAPHC (Provisional)
Jeremy	Walker	RDECOM
William	van der Schalie	USACEHR
Alan	Zulich	ECBC

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APPENDIX C

ESB SYSTEM
TECHNOLOGY ASSESSMENT
EXPERT PANEL TEAM

First Name	Last Name	Affiliation
Ric	De Leon	Metropolitan Water District of Southern California (Los Angeles, CA)
Danny	Dhanesakaran	University of Oklahoma Health Sciences Center (Oklahoma City, OK)
Jay	Dusenbury	RDECOM
Tim	Fawcett	BioSci Concepts (Baltimore, MD)
Tom	Gargan	USACEHR
Wally	Hayes	Harvard School of Public Health (Boston, MA)
Joe	Pancrazio	George Mason University (Fairfax, VA)
Vipin	Rastogi	RDECOM
Stanley	States	Pittsburgh Water and Sewer Authority (Pittsburgh, PA)
William	van der Schalie	USACEHR

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APPENDIX D

ESB SYSTEM CONCEPT OF OPERATIONS

The ESB system is being developed to provide a rapid measurement (screening) of toxicity associated with the presence of TICs in Army field drinking water supplies. The ESB system will be used by PM personnel as part of the currently used WQAS-PM. This CONOPs draws from a WQAS-PM use scenario prepared by Dr. Steve Richards and Mr. Ginn White (U.S. Army Public Health Command, provisional) and from suggestions provided by LTC William Darby (U.S. Army Medical Department Center and School).

D.1 USE OF THE ESB SYSTEM

The ESB system water testing will be conducted on raw (untreated) or processed (treated) water. The system will be operated in conjunction with other WQAS-PM test kits including the Hach Water Quality Laboratory (Loveland, CO) and Colilert (IDEXX Laboratories, Westbrook, MA) microbiological tests. The ESB system will be fielded to the brigade combat team's PM team (level II), the PM medical detachment (level III), or the area medical laboratory (level IV); other users may include water treatment operators. Soldiers operating the ESB system will include PM specialists (military occupation skill [MOS] 68S), water treatment specialists (MOS 92W), and laboratory specialists (MOS 68K). Transportation of the ESB system within theater may be by aircraft (rotary or fixed-wing) or by ground vehicles. PM teams may take the ESB system forward to the water production sites to conduct rapid screening of raw water or they may collect samples and bring them back to a fixed site for batch-sampling. The ESB system will be operational using military or civilian 110 V grid systems or internal batteries. Electrical power at the point-of-use is expected to be operational at least 75% of time. Environmental/climate control for hardware and reagents will be available, as will other WQAS-PM kit components.

D.2 FREQUENCY OF ESB SYSTEM USE

Testing for water quality parameters that are evaluated with the WQAS-PM depends on the analyzed parameter, the population size served, the water source, and the threat/risk level. Testing for chemical parameters is typically done weekly, monthly, or quarterly. Field storage containers are monitored daily for pH and chlorine residual. Testing with the ESB system is expected to be done at least weekly; although, more frequent testing may be warranted by the threat level.

D.3 USE OF ESB SYSTEM TEST RESULTS

The ESB system will be used as a rapid-screening tool for toxic contaminants in raw and product water during deployments. A negative ESB test, by itself, will not guarantee that the water is potable; no single water-quality test can do this. A positive ESB test will provide an early warning of potential health risks, which can lead to appropriate mitigation procedures. For both source and product water, a positive ESB test will indicate the need for follow-up presumptive and confirmatory testing, sanitary assessments, and possibly additional

water treatment. Retesting after action is taken can indicate whether the treatment was effective in removing toxicity. This approach is consistent with procedures already in place for the WQAS-PM kit. When the results of water testing indicate that one or more tested parameters exceed the recommended limits, PM personnel will evaluate the potential health impacts, determine a course of action, and make a recommendation to the Commander with respect to water potability and use. Possible follow-on actions might include quarantining the current water supply, retesting the water to verify results, sending a water sample to another laboratory for advanced testing, conducting a water survey to determine the potential source of the contamination and initiating corrective actions, and/or recommending an alternate water source if the problem cannot be quickly fixed.

APPENDIX E

ESB SYSTEM TECHNICAL REQUIREMENTS

No.	Category	Definition	Requirements	Comments
1	Detection	Does ESB technology/system need to provide a problem/no problem reading (similar to on/off reading) only or must it provide a gradation/sliding scale reading (e.g., detection was closer to HLC than to MEG for the short term)? No technology will provide sliding-scale readout relative to the HLC and MEG.	**(T)**: Problem/no problem reading **(O)**: Sliding-scale reading Suggestions: **(T)**: Calculated reading (output requires further analysis/computation) **(O)**: Automated readout	
2	Detection	What TICs/TIMs must the ESB technology/system must detect?** Are some types of chemicals more important to detect than others (e.g., chemicals that effect cognitive or gastrointestinal functions)? (No chemicals are currently selected as more important for identification than others.)	**(T)**: A sensor within the system must detect at least one TIC/TIM (i.e., test chemical) with one or more physiological effects **(O)**: Detect all identified test chemicals	**This requirement will be applied to the single ESB technologies under consideration for the downselection process and will be revised when the ESB system (i.e., suite of technologies) is selected.
3	Detection	The ESB technology/system must detect chemicals at what level of chemical concentration?	**(T)**: Must detect below the HLC but above the short-term MEG **(O)**: Detect at the short-term MEG level	Short-term MEG is defined as 14 day exposure and 15 L/day consumption. If information is not available, 7 day or 1 year MEG is used. MEGs have been updated to reflect TG-230 (draft) revisions.
4	Environmental Conditions During Test	ESB technology/system must be operated and stored in what air temperature and humidity level? Note: Atmospheric pressure was determined to not be an issue.	**(T)**: For equipment (same as WQAS-PM): operation at 10 to 50 °C, RH not specified; storage at –40 to 60 °C and 90% RH at 30 °C, 80% RH at 40 °C, or 70% RH at 50 °C For reagents (same as WQAS-PM reagents): operation and storage at 0 to 25 °C, RH not specified **(O)**: For equipment and reagents: operation at –20 to 50 °C, 95% RH; storage at –40 to 70 °C, 95% RH	

T: threshold or minimum requirement; O: objective or maximum requirement

No.	Category	Definition	Requirements	Comments
5	Environmental Conditions During Test	The ESB technology/system must handle what water characteristics (e.g., temperature, pH, quantity of total dissolved solids, turbidity, chlorine residual, or interferents)? Expert Panel: Is there a minimum volume of water required for the test? No per IPT (28 July 2010).	**(T)**: Temperature: 10 to 30 °C; turbidity: 10 NTU; total dissolved solids: 1500 mg/L (threshold between brackish and fresh water); pH: 5 to 9; total organic carbon: 5 mg/L; color (dissolved and suspended): 100 cu; potential interferents: chlorine residual (2 mg/L), chloramines (2 mg/L), geosmin (0.0001 mg/L), MIB (0.0001 mg/L), or blank–hard water (250 mg/L) **(O)**:Temperature: 0 to 40 °C; turbidity: 30 NTU; total dissolved solids: 30,000 mg/L; pH: 4 to 10; total organic carbon: 10 mg/L; color (dissolved and suspended): 300 cu; potential interferents: chlorine residual (10 mg/L), chloramines (10 mg/L), geosmin (0.0001 mg/L), MIB (0.0001 mg/L), or blank–hard water (250 mg/L)	Except for chlorine and chloramine, threshold and objective interference levels are the same.
6	Logistics	What are the amounts, and types of power requirements (e.g., solar, ac [110, 220], or dc [battery]) for the ESB technology?	**(T)**: Individual ESB technologies operable on military-supplied power **(O)**: ESB technologies provide an internal power source (e.g., battery, solar, manual)	
7	Physical Characteristics	What are the requirements for the ESB technology/system display (e.g., visible in low-light conditions, no sound, etc.)?	**(T)**: System must provide backlighting **(O)**: Visible in blackout conditions, with ability to mute any audible alarm. Audible alarm should also be headset-compatible	
8	Physical Characteristics	What are the maximum cubic size and weight of ESB technology/system and its associated support equipment and supplies (e.g., consumables, replacement parts, etc)?	**(T)**: Equal to the WQAS-PM light system plus incubator: ~3 cuft and ~50 lb; consumables: 40 lb **(O)**: Equal to the WQAS-PM light system plus incubator: 1 cuft and 10 lb; consumables: 5 lb	Threshold consumable weight from background document on WQAS-PM; objective consumable weight suggested to be 5 lb.
9	Robustness	Does the ESB technology/system still work if it becomes wet?	**(T)**: Electrical components should be water-resistant but not water-proof (immersion in water is not required for WQAS-PM) **(O)**: TBD (drop, vibration, EMI, and immersion tests)	Suggest revisiting objective requirements after downselection is completed. (If some technologies meet some of the objective goals [i.e., can be dropped], these goals may be further defined when performance scales are chosen for the downselection model.)

T: threshold or minimum requirement; O: objective or maximum requirement; NTU: nephelometric turbidity unit; cu: color unit; ac: alternating current; dc: direct current

No.	Category	Definition	Requirements	Comments
10	Robustness	Will TICs accumulate on a reusable ESB technology/system "test stripe" from test to test? (If yes, this may create a false positive.)	**(T)**: Not required for any component of ESB technology/system to be reusable **(O)**: Reusable and no accumulation of TICs	
11	Robustness	Does the device have an indicator that the ESB technology/system is still working (or has a malfunction signal)? Example, a process failure indicator.	**(T)**: Must have at least a set of manual steps to follow to ensure system is working properly **(O)**: Integrated, automatic indication of malfunction	
12	Robustness	What are the number of tests required before reloading or recalibrating?	**(T)**: One. Recalibrating/reloading acceptable after each test **(O)**: Multiple tests can be performed before reloading/recalibrating	
13	Robustness	What is the reliability of the ESB technology/system in terms of device failure rate per x amount of tests (i.e., hardware failure or failure <u>not</u> caused by human error or false positives/negatives)? Expert Panel: It may not be feasible to evaluate the failure rate of premature technologies. A value of 5% may be a threshold requirement that is too strict at this stage of development. Reliability may need to be evaluated on a more qualitative scale.	**(T)**: 5% failure rate **(O)**: <1% failure rate	
14	Robustness	What are the shelf lives of the device and consumables?	**(T)**: 30 days for consumables under threshold storage parameters and 1 year for hardware **(O)**: 1 year for consumables and >1 year for hardware	
15	Safety, Health, and Environmental	What are the requirements related to the safety and health of the user and to the impact on the environment? Expert Panel: The exhibition of no safety hazards may not be feasible for a threshold requirement. A more appropriate threshold would be minimal risk.	**(T)**: No safety hazard to logistics or operational personnel. HazMat below shipping declarable limits and complies with DoD HazMat directives **(O)**: No safety hazard to logistics or operational personnel and does not contain HazMats	

T: threshold or minimum requirement; O: objective or maximum requirement; TBD: to be determined; EMI: electromagnetic interference

No.	Category	Definition	Requirements	Comments
16	Testing Characteristics	Minimal false-positive and false-negative readings at the HLC (for specified chemicals that the ESB technology/system is expected to detect). False-positives and false-negatives will not be used; however a coefficient of variation (CV) will be). False negatives are of greater concern, as is reflected by a lower threshold at the objective level.	**(T)**: TBD **(O)**: TBD	Measure could be defined as a CV for the end=point variable.
17	Testing Characteristics	What is the minimum time needed between consecutive tests?	**(T)**: 1 h **(O)**: Immediate	Four technologies over 60 min.
18	Testing Characteristics	How complex is sample preparation (e.g., measured volume and reagent addition)?	**(T)**: Multiple steps of moderate complexity (e.g., requires 3 × 5 card listing steps) **(O)**: One step of low complexity	
19	Testing Characteristics	What is the test turn-around time? This includes the time from the set up and start of the test until the time results are known.	**(T)**: 8 h (based on coliform analyzer) **(O)**: <1 min	
20	Testing Characteristics	What is the operator's hands-on time to perform the set up, sample preparation and collection, and initiation of the test?	**(T)**: 1 h (does not include time to create proper sample temperature equilibration) **(O)**: <1 min	
21	User Requirements	What level of maintenance is required (includes calibration and calibration tests)?	**(T)**: Medical level maintenance **(O)**: User level maintenance	
22	User Requirements	What skills and knowledge level are required to perform ESB technology/system operations and tests?	**(T)**: At the skill/knowledge level of a 68S20 (i.e., E-5) **(O)**: At the skill/knowledge level of a 68S10 (i.e., E-4). User of WQAS-PM	

T: threshold or minimum requirement; O: objective or maximum requirement; HazMat: hazardous material; DoD: Department of Defense; CV: coefficient of variation.

APPENDIX F

ADDITIONAL INFORMATION ON MEGS

MEGs are provided for water (and other media) to estimate a level "… above which certain types of health effects may begin to occur in individuals amongst the exposed population". MEGs are "… designed to indicate 'thresholds' for minimal to no adverse health effects" and are considered "… protective against any significant non-cancer effects". MEG exposure scenarios for water are appropriate for a deployed military operation; i.e., exposure lasting either 5 or 14 days, with water consumption of either 5 or 15 L/day. The exposed population is defined to include "… relatively healthy and fit male and non-pregnant female adults", 18 to 55 years old with an average weight of 70 kg. Although MEGs are not enforceable military standards, the MEGs are considered guideline concentrations for identifying and ranking occupational and environmental health risks. MEGs have been established for about 190 chemicals, provide a reference point above which adverse effects may be expected after a field-relevant period of exposure, and may serve as lower thresholds for toxicity sensor responses. In other words, responses at concentrations below the MEGs may indicate toxic effects that may not be relevant to acute human health impairments.[‡]

[‡] U.S. Army Center for Health Promotion and Preventive Medicine. *Chemical Exposure Guidelines for Deployed Military Personnel*; TG-230; U.S. Army Center for Health Promotion and Preventive Medicine: Aberdeen Proving Ground, MD, 2001.

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APPENDIX G

ESB SYSTEM CANDIDATE AND WATCH-LISTED TECHNOLOGIES

No.	Abbreviated Name	Full Name	Evaluate Further or Move to Tech Watch List	Rationale to Move to Tech Watch List
1	Abraxis	Abraxis Organophosphate/Carbanate Screen	Evaluate Further	NA
2	ANP	ANP Acetylcholinesterase Test Kit	Evaluate Further	NA
3	Bionas	Bionas Toxicity Sensor (Trout Gill)	Evaluate Further	NA
4	ECIS (EelB)	Electric Cell Substrate Imedance Sensing (ECIS) Using Vertebrate Cells (Eel Brain)	Evaluate Further	NA
5	ECIS (Trout Gill)	Electric Cell Substrate Imedance Sensing (ECIS) Using Vertebrate Cells (Trout Gill)	Evaluate Further	NA
6	Eclox	Eclox Chemiluminescence Toxicity Test	Evaluate Further	NA
7	Melanophore	Melanophore Toxicity Sensor	Evaluate Further	NA
8	Microtox and Deltatox	Microtox (lab version) and Deltatox (field version)	Evaluate Further	NA
9	Toxichip	Toxichip (Bacterial Cells)	Evaluate Further	NA
10	TOX-SPOT	TOX-SPOT Toxicity Test	Evaluate Further	NA

NA: not applicable

No.	Abbreviated Name	Full Name	Evaluate Further or Move to Technical Watch List	Rationale to Move to Technical Watch List
11	Bionas (V79)	Bionas Toxicity Sensor (V79)	Move to Technical Watch List	Technology was not sufficiently developed. May be worth considering, if the current effort to create a fluidic chip is successful.
12	Cell Matrix Chip	Cell Matrix Chip Toxicity Sensor	Move to Technical Watch List	Technology was not sufficiently developed. Consumable shelf life is below the threshold of 1 month.
13	Chromatophore	Chromatophore Toxicity Sensor	Move to Technical Watch List	Technology was not sufficiently developed. Research to create an immortalized cell line has not yet been succesful, and the primary cells do not ship well.
14	Toxichip	Toxichip (Vertebrate Cells)	Move to Technical Watch List	Technology was not sufficiently developed. TIC/TIM detection data were not available at the time of this report. The data may be available in 5–6 months for 10 of the ESB chemicals. Approach similar to Bionas toxicity sensor should be used.
15	Water Sentinel	ICx Technologies Water Sentinel	Move to Technical Watch List	Technology was not sufficiently developed. It was not set up for quick sampling but can be used in a continuous monitoring application. Further development is continuing through a small business innovation research (SBIR) effort.
16	Yeast	Engineered Yeast	Move to Technical Watch List	Technology was not sufficiently developed. Further development will be continuing through a SBIR effort.

APPENDIX H

EXAMPLE OF AN ESB TECHNOLOGY
FACT SHEET

ANP ACETYLCHOLINESTERASE TEST KIT

(1) Technology Basics

a. Background:
This sensor technology was developed as a Phase II SBIR project. The basic reader used in the system under development was similar to the one used in the increment 1 Joint Chemical, Biological, and Radiological Agent Water Monitor.

b. Vendor:
Name: ANP Technologies, Inc.
Address: 824 Interchange Blvd., Newark, DE 19711
Phone/Fax/Email: 302 283-1730/302 283-1733/ yli@anptinc.com
Website: www.anptinc.com (accessed April 2010)

c. Technology readiness: Reagent manufacturing scale-up in progress, reader was in prototype phase (est. TRL 6).

d. Toxicity sensor type:
    i. Biological system used: Acetylcholinesterase (AchE) combined with carboxyesterase
    ii. Endpoint monitored: Inhibition of fluorescence

e. Monitoring method:
The Nano Intelligent Detection System AchE test kit is designed to detect AchE-inhibiting compounds in water. The kit uses two sequential methods to determine the presence of inhibitors. In the first method, a prepackaged unit dose of the enzyme is exposed to a water sample for 30 min and then added to a test well on the test ticket containing substrate. A clean water sample is also added to a unit dose of enzyme and then added to a control well on the ticket. The reader compares the signals on the test and control wells to determine if the enzyme has been inhibited. This method detects carbamate and many organophosphate pesticides. To detect organothiophosphate pesticides, the sample must first undergo oxidation, then reduction to neutralize the oxidation reagent. The rest of the procedure is then followed as described.

f. Cost:
    i. Cost range of basic device: handheld reader, \$3,000–\$10,000 depending on volume.
    ii. Cost range of consumables (cost per test): \$15–\$50 depending on volume.

(2) Technology Characteristics

a. Chemicals detected:

The technology response to 18 chemicals on the IPT list have been determined (Table H.1). Only range-finding tests have been conducted, and the USACEHR testing has been at the HLC only.

i. Response to 4 of 18 chemicals tested below the HLC (USACHER testing).

ii. Response to 3 of 4 organophosphate and carbamate chemicals tested in the MEG–HLC range.[§]

b. Test reproducibility (expressed as the CV for the end-point variable):

CV of 19.0% (range 15.3–22.8%), based on inhibition of fluorescence by three chemicals tested during range-finding response testing with three replicate samples per chemical. CV was given only for chemicals tested at USACEHR that exhibited a mean percent inhibition between 20–80%.

c. Susceptibility to source water conditions: very low

i. No response for pH (4.5–9), geosmin, MIB, humic/fulvic acids, or hard water.

ii. No data for turbidity, color, total dissolved solids, or total organic carbon.

iii. Product water had no response to chlorine or chloramine at 10 mg/L.

d. Susceptibility to failure:

Failure rate not yet determined.

e. Test turn-around time:

75 min

f. Environmental conditions during test: low

i. Temperature and humidity

1. Testing should be conducted at room temperature.
2. Humidity effects have not been tested because all dry reagents will be packaged in sealed foil pouches.

ii. Ability to function after becoming wet was not an issue at this stage of development.

g. Demands on the user: medium

i. Sample preparation complexity was rated as medium level because several steps are required.

ii. Level of maintenance required was rated as low because the prototype requires the manual removal of light-emitting diode (LED); however, engineering improvement was likely.

iii. Skills and knowledge required was rated as low because accurate pipetting is probably not as important as in other methods.

h. Device weight for the colorimeter:

The test kit (reader and consumables for at least 10 tests) will be packaged in a hard-shell polymer carrying case weighing 8.5 lb. Without the hard-shell carrying case, the reader and disposables weigh 3.5 lb.

i. Shelf life for consumables: medium

Consumables can be stored for an estimated 6 months at room temperature.

(3) References: None available.

[§] Vallejo, Y.R. ANP Technologies, Inc., Newark, DE. Personal communication, 2010.

Table H.1. Response to Test Chemicals

Test Chemicals	MEG	ANP Test Response (mg/L)		HLC
Acrylonitrile	0.47		>4.2[a,b]	4.2
Aldicarb	0.0047	0.1	<0.17	0.17
Ammonia	30		<924	924
Arsenic (sodium arsenite)	0.02		>4.5	4.5
Azide (sodium azide)	0.12		>47	46.7
Copper (sulfate)	1.0		<103	103
Cyanide (sodium)	2.0		>14	14
Fenamiphos	0.0042	1	>5.6	0.56
Fluoroacetate (sodium)	0.00072		3.9?	3.9
Mercuric (chloride)	0.014		>24.7	24.7
Methamidophos	0.00023	1	<1.4	1.4
Methyl parathion	0.14	0.2	<33.6	33.6
Nicotine	0.13		>16.8	16.8
Paraquat dichloride (cation)	0.047		>4.6	4.6
Pentachlorophenate (sodium)	0.023		>71.9	71.9
Phenol	2.8			91.5
Thallium (sulfate)	0.0033		>13.5	13.5
Toluene	9.3		>422	840
	References	Vallejo, Y.R. ANP Technologies, Inc., Newark, DE. Personal communication, 2010.	USACEHR, unpublished data	None

Key:	
xxx	Response concentration below MEG
xxx	Response concentration between MEG and HLC
xxx	Response concentration above HLC
	No data

[a] Values marked with > symbol: test system did not respond at the highest concentration tested and reported.
[b] Tested at HLC only.

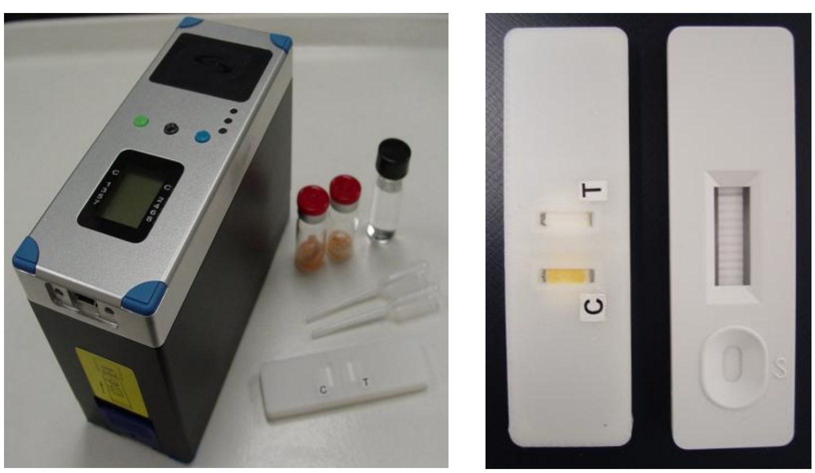

Figure H.1. ANP Prototype Reader and Cartridges.

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APPENDIX I

COMPARISON OF ESB SYSTEM TECHNICAL REQUIREMENTS TO DECISION MODEL GOALS AND CRITERIA

No.	Category	Model Goals	Model Criteria*	ESB System Technical Requirements		
				Definition	**Threshold and Objective Requirements**	**Comments**
1	Detection	NA	Not used in model Not discriminating. All technologies could be engineered to provide automated readout.	Does ESB technology/system need to provide a problem/no problem reading (similar to on/off reading) only or must it provide a gradation/sliding scale reading (e.g., detection was closer to HLC than to MEG for the short term)? No technology will provide a sliding-scale readout relative to the HLC and MEG.	**(T)**: Problem/no problem reading **(O)**: Sliding-scale reading Suggestions: **(T):** Calculated reading (output requires further analysis/computation) **(O):** Automated read-out	

* These criteria are intended for individual technologies being considered. Technologies may be combined to create the overall ESB system, and criteria will need to be revised to evaluate the system as a whole.
NA: not applicable; T: threshold or minimum requirement; O: objective or maximum requirement.
Notes: Gray shading indicates that performance requirements were not used in the evaluation model. The explanation for this exclusion is noted in the Model Criteria column.

No.	Category	Model Goals	Model Criteria*	ESB System Technical Requirements		
				Definition	Threshold and Objective Requirements	Comments
2	Detection	Performance	Chemicals Detected	What TICs/TIMs must the ESB technology/system detect?** Are some types of chemicals more important to detect than others (e.g., chemicals that effect cognitive or gastrointestinal functions)? (No chemicals are currently selected as more important for identification than others/)	**(T)**: A sensor within the system must detect at least one TIC/TIM (i.e., test chemical) with one or more physiological effects **(O)**: Detect all identified test chemicals	**This requirement will be applied to the single ESB technologies under consideration for the downselection process and will be revised when the ESB system (i.e., suite of technologies) is selected.
3	Detection	Performance	Chemicals Detected	The ESB technology/system must detect chemicals at what level of chemical concentration?	**(T)**: Must detect below the Human Lethal Concentration (HLC), but above the short-term MEG **(O)**: Detect at the short-term MEG level	Short-term MEG is defined as 14-day exposure and 15 L/day consumption; if not available, 7- day or 1-year MEG is used. MEGs have been updated to reflect TG-230 (draft) revisions.
4	Environmental Conditions During Test	Operational Impact	Environmental Conditions During Testing	ESB technology/system be operated and stored in what air temperature and humidity level? Note: Atmospheric pressure was determined to not be an issue.	**(T)**: For equipment (same as WQAS-PM): operation as 10 to 50 °C, RH not specified; storage at –40 to 60 °C and 90% RH at 30 °C, 80% RH at 40 °C, and 70% RH at 50 °C For reagents (same as WQAS-PM reagents): operation and storage at 0 to 25 °C, RH not specified **(O)**: For equipment and reagents: operation at –20 to 50 °C, 95% RH; storage at –40 to 70 °C, 95% RH	

* These criteria are intended for individual technologies being considered. Technologies may be combined to create the overall ESB system, and criteria will need to be revised to evaluate the system as a whole.
NA: not applicable; T: threshold or minimum requirement; O: objective or maximum requirement.
Notes: Gray shading indicates that performance requirements were not used in the evaluation model. The explanation for this exclusion is noted in the Model Criteria column.

No.	Category	Model Goals	Model Criteria*	ESB System Technical Requirements		
				Definition	Threshold and Objective Requirements	Comments
5	Environmental Conditions During Test	Performance	Susceptibility to Source Water Conditions	The ESB technology/system must handle what water characteristics (e.g., temperature, pH, quantity of total dissolved solids, turbidity, chlorine residual, or interferents)? Expert Panel: Is there a minimum volume of water required for the test? No per IPT (28 July 2010)	**(T)**:Temperature: 10 to 30 °C; turbidity: 10 NTU; total dissolved solids: 1500 mg/L (threshold between brackish and fresh water); pH: 5 to 9; total organic carbon: 5 mg/L; color (dissolved and suspended): 100 cu; potential interferents: chlorine residual (2 mg/L), chloramines (2 mg/L), geosmin (0.0001 mg/L), MIB (0.0001 mg/L), or blank–hard water (250 mg/L) **(O)**:Temperature: 0 to 40 °C; turbidity: 30 NTU; total dissolved solids: 30,000 mg/L; pH: 4 to 10; total organic carbon: 10 mg/L; color (dissolved and suspended): 300 cu; potential interferents: chlorine residual (10 mg/L), chloramines (10 mg/L), geosmin (0.0001 mg/L), MIB (0.0001 mg/L), or blank–hard water (250 mg/L)	Except for chlorine and chloramine, threshold and objective interference levels are the same.
6	Logistics	NA	Not used in model Not discriminating. All technologies could be engineered to operate on internal power (i.e., battery)	What are the amounts and types of power requirements (e.g., solar, ac [110, 220], or dc [battery]) for the ESB technology?	**(T)**: Individual ESB technologies operable on military-supplied power **(O)**: ESB technologies provide an internal power source (e.g., battery, solar, manual)	

* These criteria are intended for individual technologies being considered. Technologies may be combined to create the overall ESB system, and criteria will need to be revised to evaluate the system as a whole.
NA: not applicable; T: threshold or minimum requirement; O: objective or maximum requirement.
Notes: Gray shading indicates that performance requirements were not used in the evaluation model. The explanation for this exclusion is noted in the Model Criteria column.

No.	Category	Model Goals	Model Criteria*	ESB System Technical Requirements		
				Definition	Threshold and Objective Requirements	Comments
7	Physical Characteristics	NA	Not used in model Not discriminating. All technologies could be engineered to meet objective requirement	What are the requirements for the ESB technology/ system display requirements (e.g., visible in low-light conditions, no sound, etc.)?	**(T)**: System must provide backlighting **(O)**: Visible in blackout conditions, with ability to mute any audible alarm. Audible alarm should also be headset-compatible	
8	Physical Characteristics	Logistics	Weight	What are the maximum cubic size and weight of ESB technology/system and its associated support equipment and supplies (e.g., consumables, replacement parts, etc.)?	**(T)**: Equal to the WQAS-PM light system plus incubator: ~3 cuft and ~50 lb; consumables: 40 lb **(O)**: Equal to the WQAS-PM light system plus incubator: 1 cuft and 10 lb; consumables: 5 lb	Threshold consumable weight from background document on WQAS-PM; objective consumable weight suggested to be 5 lb
9	Robustness	Operational Impact	Environmental Conditions During Testing	Does the ESB technology/ system still work if it becomes wet?	**(T)**: Electrical components should be water-resistant but not water-proof (immersion in water is not required for WQAS-PM) **(O)**: TBD (drop, vibration, EMI, and immersion tests)	Suggest revisiting objective requirements after downselection is completed. (If some technologies meet some of the objective goals [i.e., can be dropped] these goals may be further defined when performance scales are chosen for the downselection model.)
10	Robustness	NA	Not used in model. Not discriminating. None of the technologies are reusable	Will TICs accumulate on a reusable ESB technology/ system “test stripe” from test to test? (If yes, this may create a false positive.)	**(T)**: Not required for any component of ESB technology/ system to be reusable **(O)**: Reusable and no accumulation of TICs	

* These criteria are intended for individual technologies being considered. Technologies may be combined to create the overall ESB system, and criteria will need to be revised to evaluate the system as a whole.
NA: not applicable; T: threshold or minimum requirement; O: objective or maximum requirement; TBD: to be determined; EMI: electromagnetic interference.
Notes: Gray shading indicates that performance requirements were not used in the evaluation model. The explanation for this exclusion is noted in the Model Criteria column.

No.	Category	Model Goals	Model Criteria*	ESB System Technical Requirements		
				Definition	**Threshold and Objective Requirements**	**Comments**
11	Robustness	NA	Not used in model Not discriminating. All technologies could be engineered to have an automatic, positive-control indicator	Does the device have an indicator that the ESB technology/system is still working (or has a malfunction signal)? Example, a process failure indicator	**(T)**: Must have at least a set of manual steps to follow to ensure system is working properly **(O)**: Integrated, automatic indication of malfunction	
12	Robustness	Operational Impact	Not used in model Provides limited discrimination. Too early to determine answer for many ESB sensors. All sensors could be engineered to require less reloading and recalibration	What is the number of tests required before reloading, or recalibrating?	**(T)**: One. Recalibrating/reloading acceptable after each test **(O)**: Multiple tests can be performed before reloading/recalibrating	
13	Robustness	Performance	Susceptibility to failure (reliability) Not used in model Insufficient data	What is the reliability of the ESB technology/system in terms of device failure rate per x amount of tests (i.e., hardware failure or failure <u>not</u> caused by human error or false positives/negatives)? Expert Panel: It may not be feasible to evaluate the failure rate of premature technologies. A value of 5% may be a threshold requirement that is too strict at this stage of development. Reliability may need to be evaluated on a more qualitative scale.	**(T)**: 5% failure rate **(O)**: <1% failure rate	

* These criteria are intended for individual technologies being considered. Technologies may be combined to create the overall ESB system, and criteria will need to be revised to evaluate the system as a whole.
NA: not applicable; T: threshold or minimum requirement; O: objective or maximum requirement.
Notes: Gray shading indicates that performance requirements were not used in the evaluation model. The explanation for this exclusion is noted in the Model Criteria column.

No.	Category	Model Goals	Model Criteria*	ESB System Technical Requirements		
				Definition	Threshold and Objective Requirements	Comments
14	Robustness	Logistics	Shelf Life	What are the shelf lives of the device and consumables?	**(T)**: 30 days for consumables under threshold storage parameters and 1 year for hardware **(O)**: 1 year for consumables and >1 year for hardware	
15	Safety, Health, and Environmental	NA	Not used in model Not discriminating. All technologies are essentially safe using basic laboratory safety equipment (e.g., gloves and safety glasses) and by following basic safety procedures and requirements	What are the requirements related to the safety and health of the user and to the impact on the environment? Expert Panel: The exhibition of no safety hazards may not be feasible for a threshold requirement. A more appropriate threshold would be minimal risk	**(T)**: No safety hazard to logistics or operational personnel. HazMat below shipping declarable limits and complies with DoD HazMat directives **(O)**: No safety hazard to logistics or operational personnel and does not contain HazMats	
16	Testing Characteristics	Performance	Test Reproducibility Not used in model Insufficient data	Minimal false-positive and false-negative readings at the HLC (for specified chemicals that the ESB technology/ system is expected to detect). False-positives and false-negatives will not be used; however, a CV will be used. False negatives are of greater concern, as is reflected by a lower threshold at the objective level.	**(T)**: TBD **(O)**: TBD	Measure could be defined as a CV for the end-point variable.

* These criteria are intended for individual technologies being considered. Technologies may be combined to create the overall ESB system, and criteria will need to be revised to evaluate the system as a whole.

T: threshold or minimum requirement; O: objective or maximum requirement; HazMat: hazardous material; DoD: Department of Defense; CV: coefficient of variation; TBD: to be determined.

Notes: Gray shading indicates that performance requirements were not used in the evaluation model. The explanation for this exclusion is noted in the Model Criteria column.

No.	Category	Model Goals	Model Criteria*	ESB System Technical Requirements		
				Definition	Threshold and Objective Requirements	Comments
17	Testing Characteristics	Operational Impact	Test Turn Around Time Not used in model Provides limited discrimination among options compared to just using “first test” turn-around time.	What is the minimum time between consecutive tests?	**(T)**: 1 h **(O)**: Immediate	Four technologies over 60 min
18	Testing Characteristics	Operational Impact	Demands on the User	How complex is sample preparation (e.g., measured volume and reagent addition)?	**(T)**: Multiple steps of moderate complexity (e.g., requires 3 × 5 card listing steps) **(O)**: One step of low complexity	
19	Testing Characteristics	Operational Impact	Test Turn-Around Time	What is the test turn-around time? This includes the time from the setup and start of the test until the time results are known.	**(T)**: 8 h (based on coliform analyzer) **(O)**: <1 min	
20	Testing Characteristics	Operational Impact	Demands on the User	What is the operator’s hands-on time to perform the set up, sample preparation and collection, and initiation of the test?	**(T)**: 1 h (does not include time to create proper sample temperature equilibration) **(O)**: <1 min	
21	User Requirements	Operational Impact	Demands on the User	What level of maintenance is required (includes calibration and calibration tests)?	**(T)**: Medical level maintenance **(O)**: User level maintenance	
22	User Requirements	Operational Impact	Demands on the User	What skills and knowledge level are required to perform ESB technology/system operations and tests?	**(T)**: At the skill/knowledge level of a 68S20 (i.e., E-5) **(O)**: At the skill/knowledge level of a 68S10 (i.e., E-4). User of WQAS-PM	

* These criteria are intended for individual technologies being considered. Technologies may be combined to create the overall ESB system, and criteria will need to be revised to evaluate the system as a whole.
T: threshold or minimum requirement; O: objective or maximum requirement.
Notes: Gray shading indicates that performance requirements were not used in the evaluation model. The explanation for this exclusion is noted in the Model Criteria column.

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APPENDIX J

ESB SYSTEM PROGRAMMATICS ASSESSMENT

Technologies	TRL	Reasonable\Expected Improvements (Upside)	Concerns (Known)	Risks (Unknown)	Overall Risk
Abraxis	Commercially available (CA)	The complexity of the Abraxis technology, including test turn-around time, can be reduced; however, the company would have to agree. It is possible that the company would agree, depending on market viability.	This technology detects chemicals it is not intended to (albeit at relatively high concentrations). This technology will have problems with sulfur-containing source water.	May have problems due to using a visible light detection approach.	Y
ANP	6	Additional testing will be needed to define where the ANP technology responds within the MEG–HLC range. The operational temperature range could be improved. TRL 6 level provides an opportunity for modifications. This could be a dual-use technology (i.e., detecting CWAs).			G
Bionas	Research system - CA Field-suitable system - 4	Because the Bionas technology was in early development, improvement was expected in areas where it scored low (weight, test time, and demands on the user).	Future improvements are dependent on successful new fluidic chip design (expected new information in 3–4 months). Foreign company.		R
ECIS (EelB)	3/4	Storage tests performed with the ECIS EelB to date have not been longer than a month. This will be evaluated to see if storage time can be longer than currently scored. Assay temperature range assessed to date has been limited and could be greater. There is potential for more than one cell type on a chip (although this would increase cost).	Using biological components, made by a university or individual researcher, makes the eel-based system riskier and it may be less robust. There is a need to evaluate optimal storage temperature, to complete detection-level testing, and to characterize the cell line.	Cells respond to many things, which cause an interference issue and false positives.	Y/R
ECIS (Trout Gill)	4/5	Storage tests performed with the ECIS Trout Gill to date have not been longer than 8 months. This will be evaluated to see if storage time can be longer than currently scored. Assay temperature range assessed to date has been limited and could be lower than room temperature. There is potential for more than one cell type on a chip (although this would increase cost).		Cells respond to many things, which cause an interference issue and false positives. (Trout Gill causes fewer issues than ECIS EelB).	G/Y

Potential Risk Assessment:	
Green (G)	The technology is considered to present a low risk of unsuccessful development.
Yellow (Y)	The technology is considered to present a moderate risk of unsuccessful development.
Red ®	The technology is considered to present a high risk of unsuccessful development.

Technologies	TRL	Reasonable\Expected Improvements (Upside)	Concerns (Known)	Risks (Unknown)	Overall Risk
Toxichip	4	Toxichip is a research grade instrument, and its weight is expected to decrease with further development. Temperature range is expected to be at least 25–40 °C. Sensitivity to remaining chemicals will be determined by further testing (only tested nine chemicals).	All data was vendor-provided and needs to be validated. Toxichip technology has a short shelf life, although it could be lengthened. Genetically engineered bacteria that is developed outside of U.S. in an academic environment can have concerns regarding availability and can have unknown sensitivity to unknown interferents. Lack of data for sensitivity to source water conditions.	Could pose potential adverse health effects to user due to genetically engineered bacteria.	R
ESB Technologies Not Under Further Consideration					
Deltatox	CA		The Deltatox technology requires freezing for optimal shelf life, which is a very serious concern (i.e., a show-stopper). Maintaining freezing conditions during the shipping process is very problematic (can take up to a month). ESB technology/sensor and consumables will not have same priority as other items, such as shipping blood.		No further consideration
Eclox	CA		The Eclox technology only detects three test chemicals and two were below MEG.		No further consideration
Melanophore	5	With more testing, there is a possibility of improvement in chemical detection using the Melanophore. Test turn-around time should improve.	This technology had a lack of data for sensitivity to source water conditions. The 3 month shelf life (driven by biology) eliminates this technology from further consideration.	Problem with access to cells (industrial proprietary cell line that is not for sale.	No further consideration
TOX-SPOT	CA		This technology requires freezing for optimal shelf life, which is a very serious concern (i.e., a show-stopper). Maintaining freezing conditions during the shipping process is very problematic (can take up to a month). ESB technology/ sensor and consumables will not have same priority as other items, such as shipping blood.		No further consideration
Potential Risk Assessment:					
Green (G)	The technology is considered to present a low risk of unsuccessful development.				
Yellow (Y)	The technology is considered to present a moderate risk of unsuccessful development.				
Red ®	The technology is considered to present a high risk of unsuccessful development.				

APPENDIX K

ESB SYSTEM TECHNOLOGY STRENGTHS AND WEAKNESSES ANALYSIS CHARTS

The purpose of this technology analysis was to highlight areas where particular ESB technologies stood out, either positively or negatively.

Figures K.1 to K.10 depict the strengths and weaknesses for each of the ten ESB technologies relative to the eight criteria/measures in the model. The height of the bars indicates a technology's relative score for each measure, and the width indicates the relative weight of the measure. For example, the ECIS (EelB) technology scored 100 against two measures *(Chem Detect HLC* and *Demands on User)* and almost 100 for the *Weight* measure. The *Chem Detect HLC* measure was the highest weighted measure. Two of the three measures where ECIS (EelB) scored 0 (*Environ Cond/Temp, Suscept SW Cond*) were weighted very low at 5 and 2%. The charts are presented in the order of overall technology ranking results from best to worst.

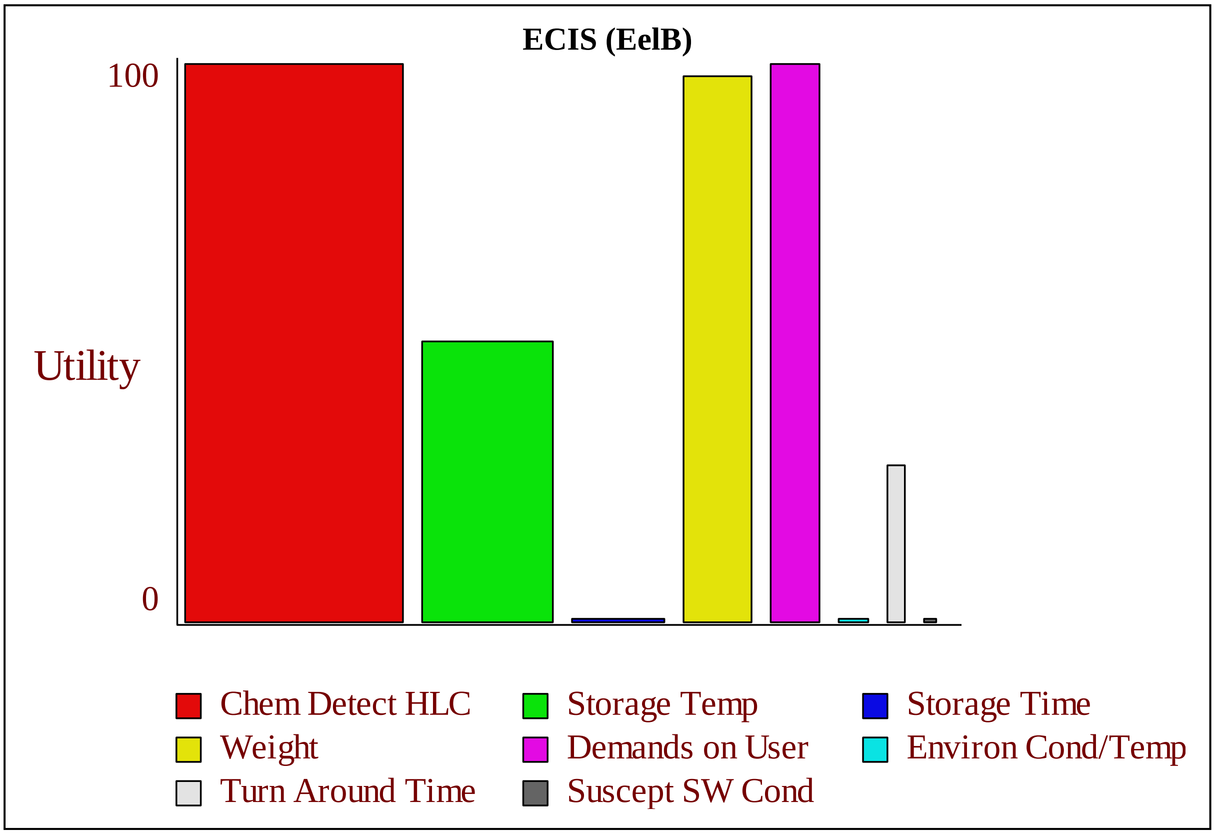

Figure K.1. ECIS (EelB) strengths and weakness chart.

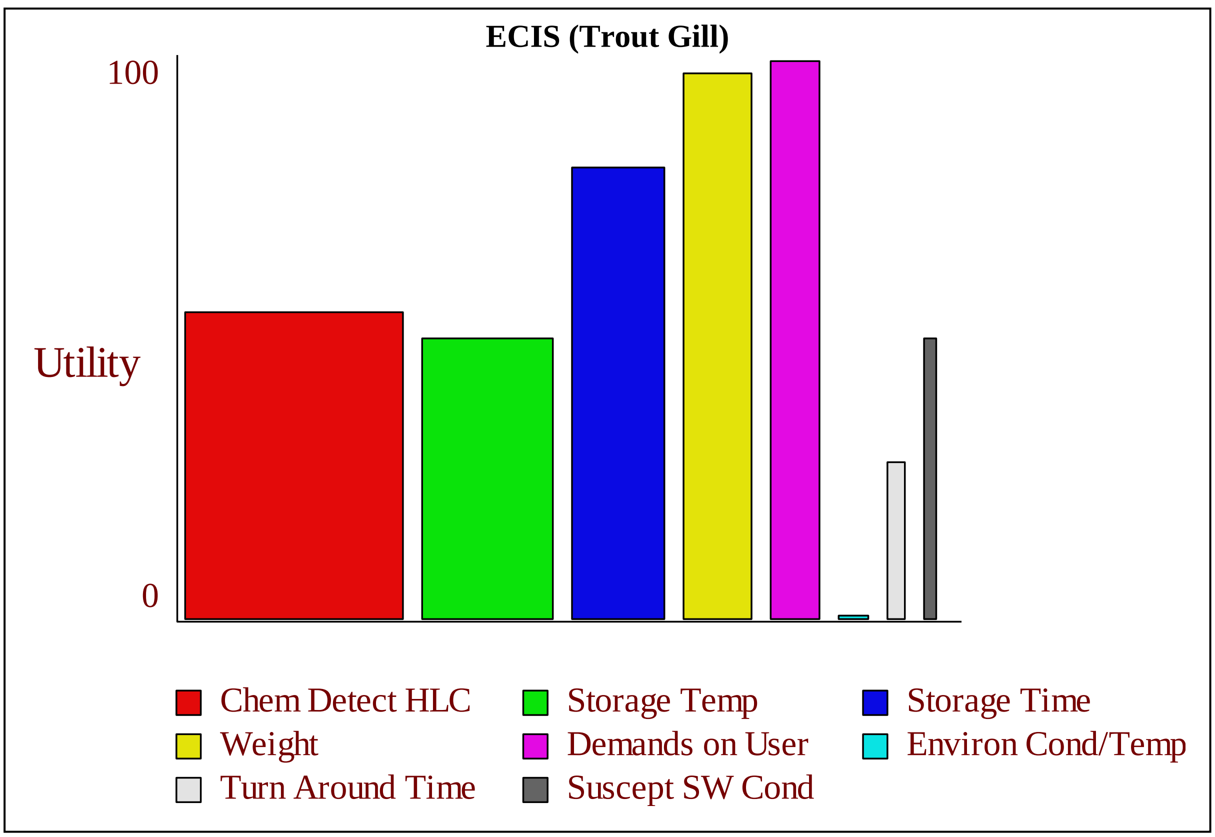

Figure K.2. ECIS (Trout Gill) strengths and weakness chart.

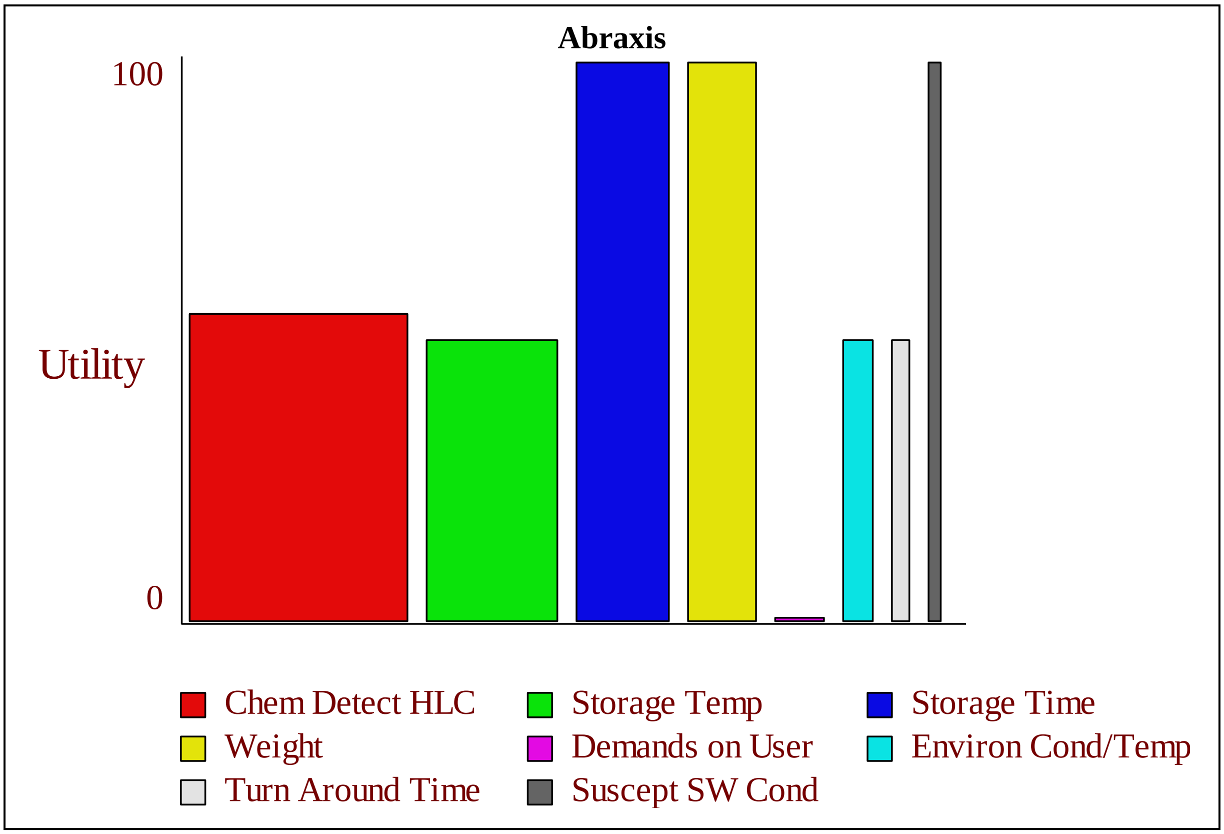

Figure K.3. Abraxis strengths and weakness chart.

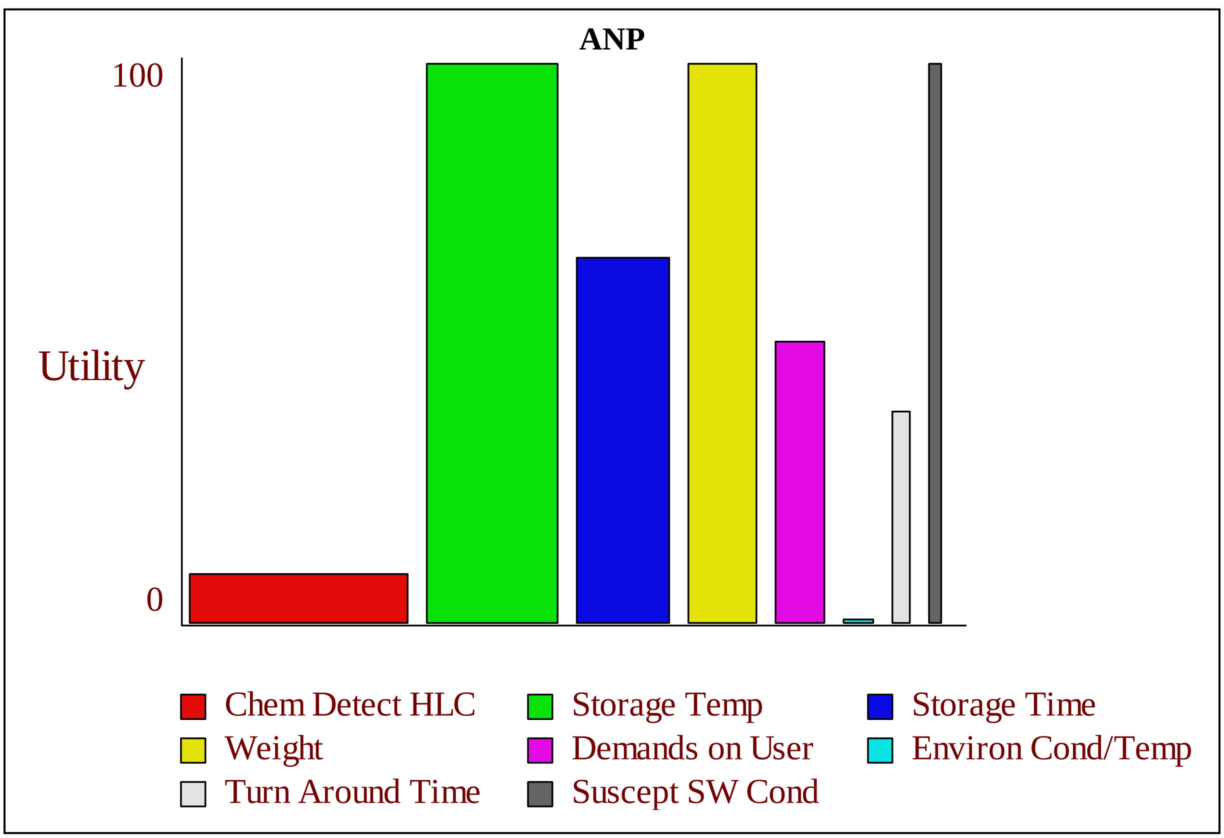

Figure K.4. ANP strengths and weakness chart.

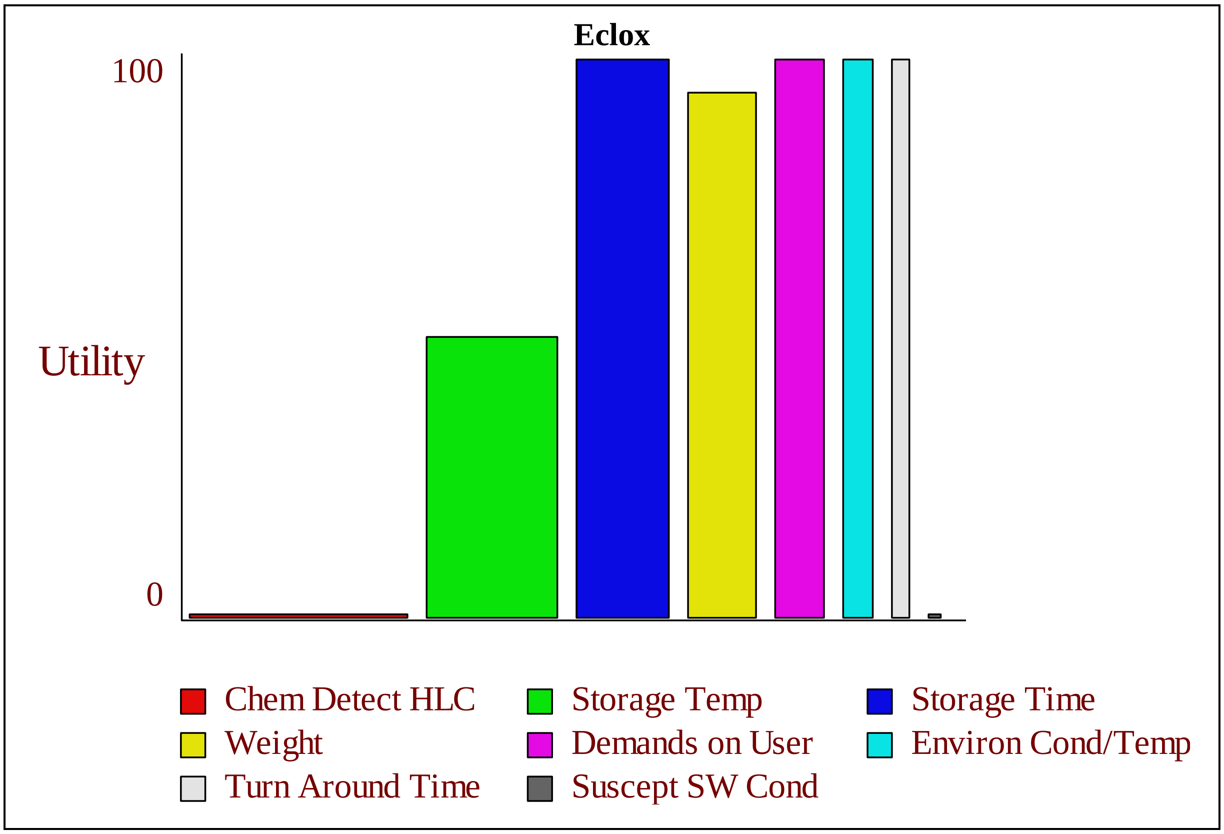

Figure K.5. Eclox strengths and weakness chart.

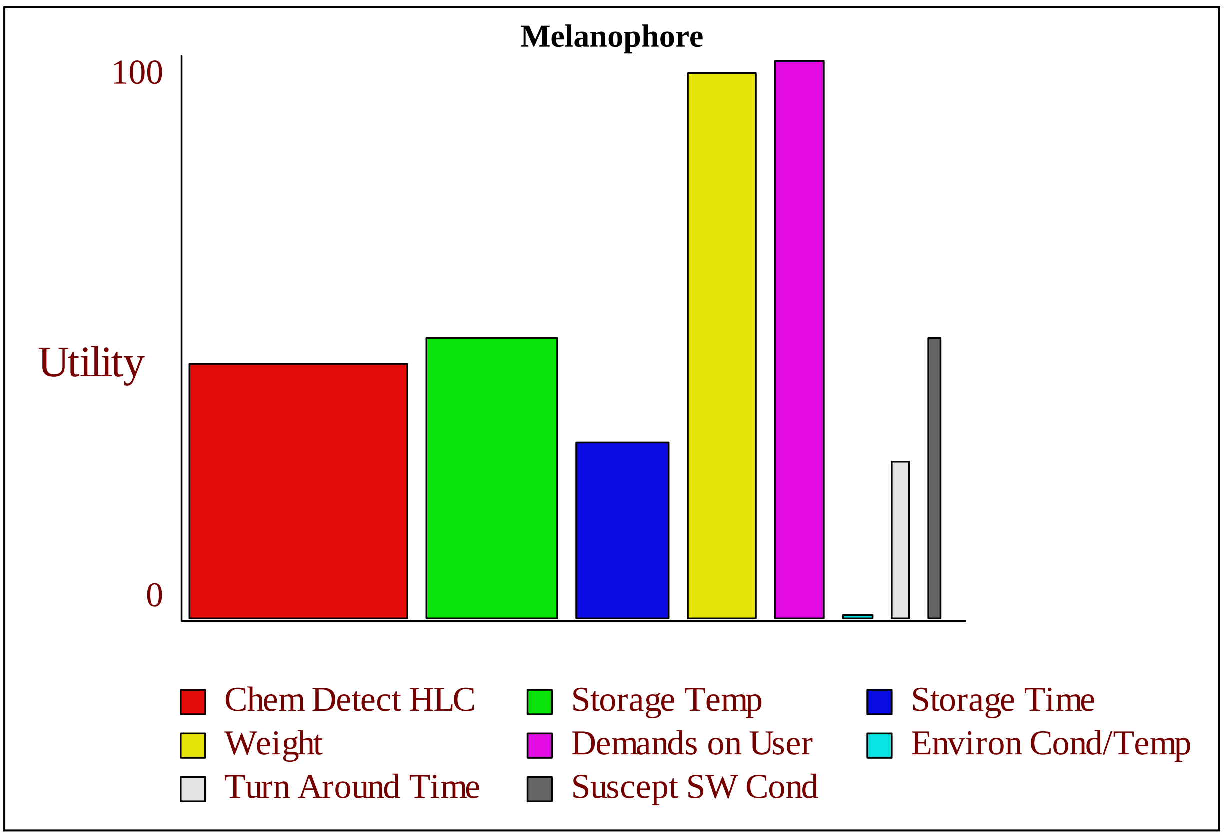

Figure K.6. Melanophore strengths and weakness chart.

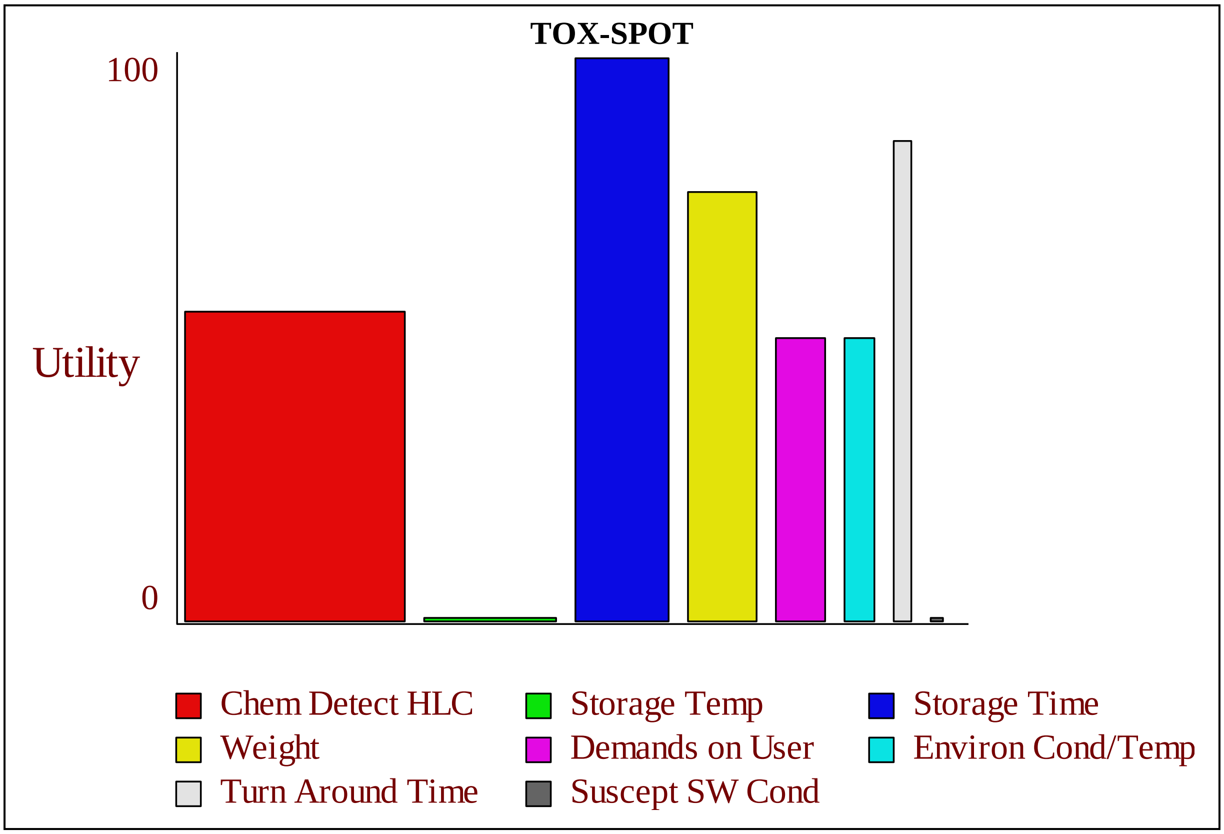

Figure K.7. TOX-SPOT strengths and weakness chart.

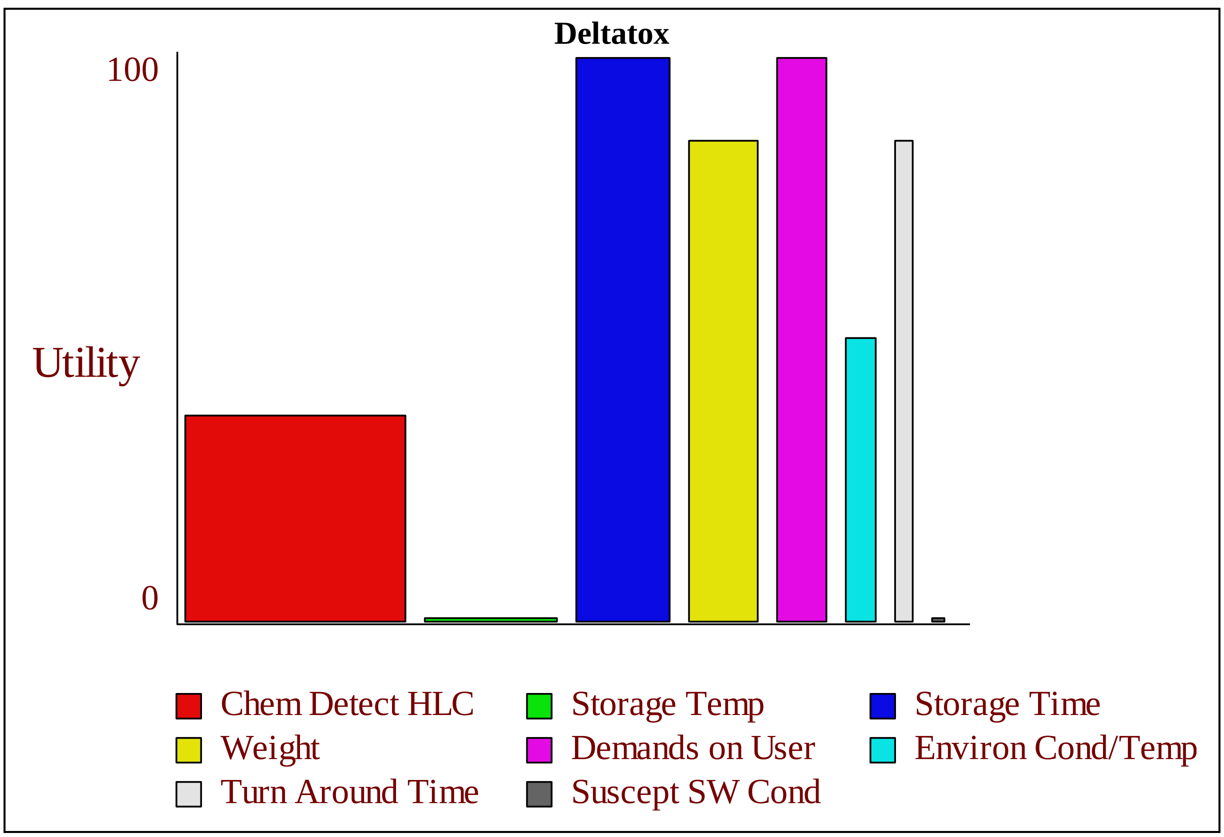

Figure K.8. Deltatox strengths and weakness chart.

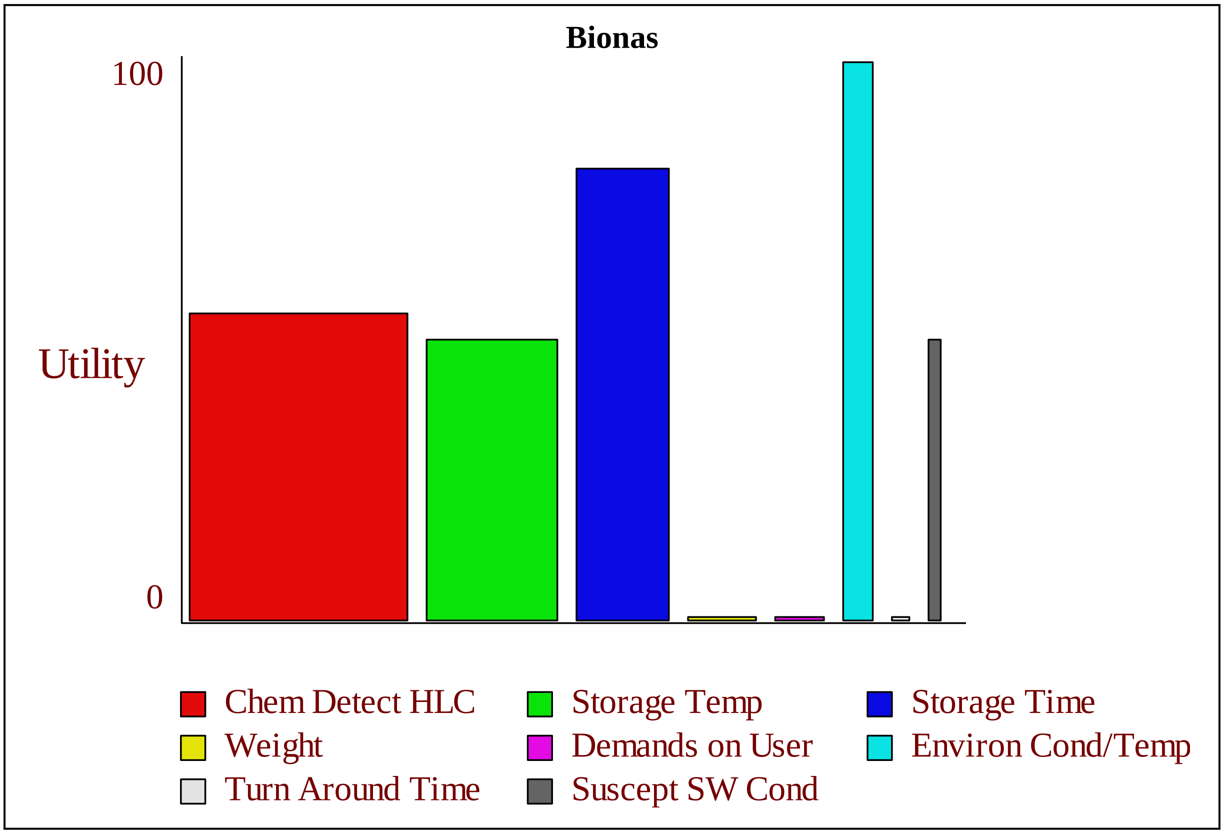

Figure K.9. Bionas strengths and weakness chart.

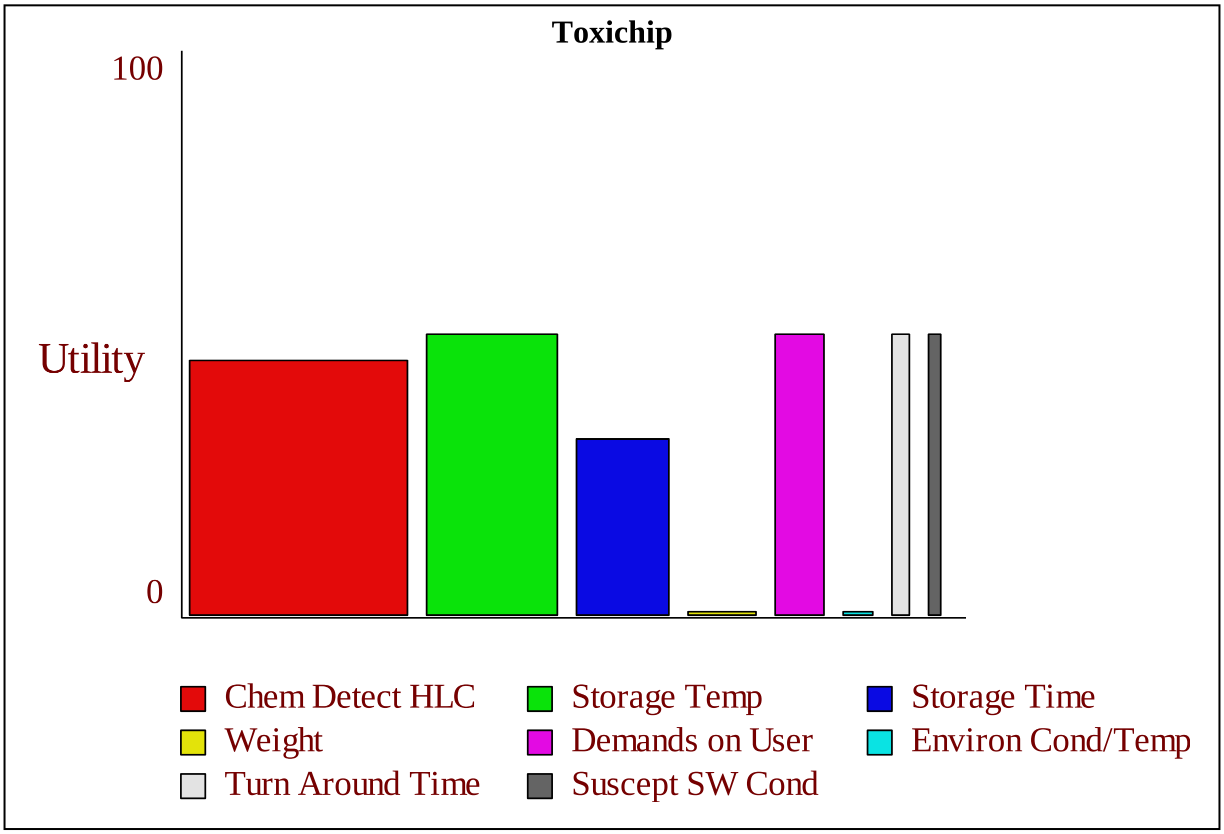

Figure K.10. Toxichip strengths and weakness chart.

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